As filed with the Securities and Exchange Commission on June 22, 2020

Registration Statement No. 333-238829

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

Amendment No. 1

to

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GREENWICH LIFESCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	20-5473709
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3992 Bluebonnet Dr, Building 14
Stafford, TX 77477
(832) 819-3232
(Address and telephone number of registrant's principal executive offices)

Snehal Patel
Chief Executive Officer
Greenwich LifeSciences, Inc.
3992 Bluebonnet Dr, Building 14
Stafford, TX 77477
(832) 819-3232
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jeffrey J. Fessler, Esq. **Nazia J. Khan, Esq.** **Sheppard, Mullin, Richter & Hampton LLP** **30 Rockefeller Plaza** **New York, NY 10112-0015** **Tel.: (212) 653-8700**	**Gregory Sichenzia, Esq.** **Darrin Ocasio, Esq.** **Sichenzia Ross Ference LLP** **1185 Avenue of the Americas, 37th Floor** **New York, NY 10036** **Tel.: (212) 930-9700**

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the 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 to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[2]
Common Stock, par value $0.001 per share	$ 9,200,000	$ 1,194.16
Warrants to purchase common stock to be issued to the Underwriter[3][4]	—	—
Common stock issuable upon exercise of warrants to purchase common stock to be issued to the Underwriter[3][5]	$ 800,000	$ 103.84
Common Stock, par value $0.001 per share offered by the selling stockholders	$ 13,483,152	$ 1,750.11
Total:	$ 23,483,152	$ 3,048.11*

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of the securities registered hereunder to be sold by the registrant.

(3) We have agreed to issue to the underwriters, upon closing of this offering, warrants to purchase 8% of the number of shares of common stock sold in this offering (excluding shares of common stock sold to cover over-allotments, if any). Resales of shares of common stock issuable upon exercise of the underwriter warrants are being similarly registered on a delayed or continuous basis. We have calculated the proposed maximum aggregate offering price of the common stock underlying the underwriter's warrants by assuming that such warrants are exercisable at a price per share equal to 125% of the price per share sold in this offering.

(4) No fee required pursuant to Rule 457(g).

(5) Pursuant to Rule 416 under the Securities Act, there is also being registered hereby such indeterminate number of additional shares of common stock of the Registrant as may be issued or issuable because of stock splits, stock dividends, stock distributions, and similar transactions.

* Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Registration Statement contains two forms of prospectuses: one to be used in connection with the initial public offering of 1,150,000 shares of our common stock (including shares of common stock which may be issued on exercise of a 45-day option granted to the underwriters to cover over-allotments, if any) through the underwriters named on the cover page of this prospectus (the "IPO Prospectus") and one to be used in connection with the potential resale by certain selling stockholders of an aggregate amount up to 1,685,394 shares of our common stock (the "Selling Stockholder Prospectus"). The IPO Prospectus and the Selling Stockholder Prospectus will be identical in all respects except for the alternate pages for the Selling Stockholder Prospectus included herein which are labeled "Alternate Pages for Selling Stockholder Prospectus."

The Selling Stockholder Prospectus is substantively identical to the IPO Prospectus, except for the following principal points:

- they contain different outside and inside front covers;
- they contain different Offering sections in the Prospectus Summary section;
- they contain different Use of Proceeds sections;
- the Capitalization section is deleted from the Selling Stockholder Prospectus;
- the Dilution section is deleted from the Selling Stockholder Prospectus;
- a Selling Stockholder section is included in the Selling Stockholder Prospectus;
- the Underwriting section from the IPO Prospectus is deleted from the Selling Stockholder Prospectus and a Plan of Distribution is inserted in its place; and
- the Legal Matters section in the Selling Stockholder Prospectus deletes the reference to counsel for the underwriters.

We have included in this Registration Statement, after the financial statements, a set of alternate pages to reflect the foregoing differences of the Selling Stockholder Prospectus as compared to the IPO Prospectus.

While the selling stockholders have expressed an intent not to sell the shares of common stock registered pursuant to the Selling Stockholder Prospectus concurrently with the initial public offering, the sales of our common stock registered in the IPO Prospectus and the Selling Stockholder Prospectus may result in two offerings taking place concurrently, which could affect the price and liquidity of, and demand for, our common stock. This risk and other risks are included in "Risk Factors" beginning on page 10 of the IPO Prospectus.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated June 22, 2020

PROSPECTUS

1,000,000 Shares

Greenwich LifeSciences

Common Stock

This is the initial public offering of shares of common stock of Greenwich LifeSciences, Inc. We are offering 1,000,000 shares of our common stock. No public market currently exists for our stock. We anticipate that the initial public offering price will be between $7.50 and $8.50 per share.

We have applied to list our shares on The Nasdaq Capital Market under the symbol "GLSI."

In addition, we have registered an aggregate of 1,685,394 shares of our common stock for resale by certain selling stockholders by means of the Selling Stockholder Prospectus. While the selling stockholders have expressed an intent not to sell the shares of common stock registered pursuant to the Selling Stockholder Prospectus concurrently with the initial public offering, sales of the shares of our common stock registered in this prospectus and the Selling Stockholder Prospectus may result in two offerings taking place concurrently which might affect price, demand, and liquidity of our common stock.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 10.

	Per Share	Total
Price to the public	$	$
Underwriting discounts and commissions	$	$
Proceeds to us (before expenses)[1]	$	$

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(1) Does not include a non-accountable expense allowance equal to 1.0% of the gross proceeds of this offering payable to the underwriters. We refer you to "Underwriting" beginning on page 100 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters a 45-day option to purchase up to 150,000 additional shares at the initial public offering price, less the underwriting discount.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about , 2020.

Prospectus dated , 2020

Aegis Capital Corp.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The selling stockholders are offering to sell and seeking offers to buy our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless context requires otherwise, references to "we," "us," "our," "GLSI" "Greenwich LifeSciences," or "the Company" refer to Greenwich LifeSciences, Inc.

Overview

We are a biopharmaceutical company developing GP2, an immunotherapy designed to prevent the recurrence of breast cancer following surgery. GP2 is a 9 amino acid transmembrane peptide of the HER2/*neu* (human epidermal growth factor receptor 2) 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. In a Phase IIb clinical trial 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. We are planning to commence a Phase III clinical trial in 2020.

Substantial Unmet Need

Following breast cancer surgery, a HER2/*neu* 3+ patient receives Herceptin in the first year, with the hope that their breast cancer will not recur, with the odds of recurrence slowly decreasing over the first 5 years after surgery. Herceptin has been shown to reduce recurrence rates from 25% to 12% in the adjuvant setting while Kadcyla has been shown to reduce recurrence rates from 22% to 11% in the neoadjuvant setting. Accordingly, we believe that GP2 may be used to address the 50% of recurring patients who do not respond to either Herceptin or Kadcyla. In the neoadjuvant setting, a patient receives treatment before surgery and, based on the results of a biopsy at surgery, will receive the same or more potent treatment after surgery.

GP2 is administered in combination with the immunoadjuvant GM-CSF in years 2-4, following the first year of treatment with Herceptin, in a series of 11 intradermal injections comprising 6 primary injections over 6 months (1 injection per month) followed by 5 booster injections every 6 months thereafter. Furthermore, we believe that recently approved drugs such as Perjeta and Nerlynx do not fully address this unmet need, even in their most efficacious subpopulations, and that in the initial GP2 indication, approximately 17,000 new patients may be eligible for GP2 treatment per year, which could save approximately 1,500 to 2,000 lives per year.

Statistically Significant Phase IIb Clinical Data in HER2/neu 3+ Over-Expressors

In a randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial of HLA-A02 breast cancer patients, the combination of GP2-GMCSF-Herceptin treatment resulted in no recurrences in 46 HER2/*neu* 3+ over-expressor patients who were fully treated with GP2 versus 50 placebo patients who were treated with GMCSF-Herceptin and who recurred at a rate similar to historical recurrence rates for patients treated with Herceptin. After median 5 years of follow-up, there were 0% cancer recurrences in the HER2/*neu* 3+ patients treated with GP2-GMCSF-Herceptin, if the patient received the 6 primary intradermal injections over the first 6 months, versus an 11% cancer recurrence rate in the placebo arm treated with GMCSF-Herceptin ($p = 0.0338$). Thus, sequentially combining Herceptin in year 1 and GP2-GMCSF in years 2-4 may dramatically lower breast cancer recurrences in this patient population.

Potent Immune Response

In the Phase IIb clinical trial, GP2 immunotherapy elicited a potent immune response in HLA-A02 patients after they received the 6 primary intradermal injections over the first 6 months. The immune response was measured by a local skin test and immunological assays. Further, booster injections given every 6 months thereafter prolonged the immune response, thereby providing longer term protection.

Well Tolerated Safety Profile

In the Phase IIb and three Phase I clinical trials where 138 patients received GP2 immunotherapy, there were no reported serious adverse events ("SAEs") related to GP2 treatment.

Upcoming Phase III Clinical Trial

We are planning to launch a Phase III clinical trial in 2020, using a similar treatment regime as the Phase IIb clinical trial. The manufacturing plan and the Phase III trial protocol have been reviewed by the FDA and final revisions to the Phase III trial protocol are under way, which may include an interim analysis/adaptive trial design. Furthermore, we have commenced GP2 manufacturing, and we are currently in the process of finalizing our engagement of contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, for the Phase III clinical trial.

License & Intellectual Property

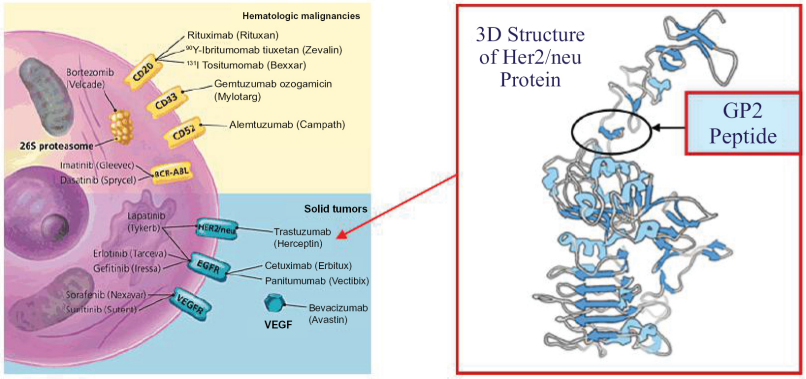
The Henry M. Jackson Foundation, or HJF, out-licenses technology of the United States military and it conducts research and manages clinical trials. We entered into an exclusive license agreement with HJF pursuant to which we have been granted an exclusive worldwide license to GP2. The GP2 issued patents provide protection ranging from 2026 through 2032 in major markets such as the U.S., Europe, Japan, Australia, and Canada, with ongoing prosecution in other markets. We plan to register GP2 as a biologic, which may be subject to 10-12 years market exclusivity in the U.S. upon receiving marketing approval.

Large Initial & Expandable Breast Cancer Market

We believe that the potential market for the proposed initial and follow-on indications is large. HER2/*neu* 3+ breast cancer patients comprise approximately 25% of all breast cancer patients. Approximately 40% to 50% of the U.S. population contains the HLA-A02 allele, while node positive and high risk node negative patients comprise approximately 50% of the market. Therefore, we believe that the initial market for GP2 could be the combination of the three populations above which together comprises 6% of breast cancer patients. We believe that follow-on indications could include additional HLA types (an additional 30% of the U.S. population) and the low to intermediate expressors of HER2/*neu* 1-2+ patients (an additional 50% of all breast cancer patients) which would expand the GP2 market from our estimated initial 6% to 30% of breast cancer patients who undergo surgery. Thus the market for GP2, including follow-on indications, could be 2.4 times the current Herceptin adjuvant setting market, which constitutes approximately 12.5% of breast cancer patients.

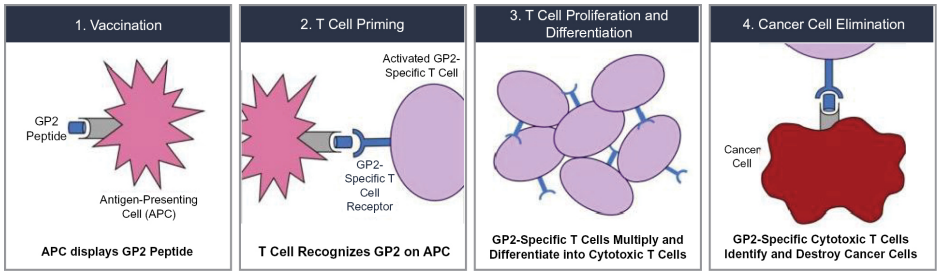
Our Product Candidate

GP2 is a HER2/*neu* transmembrane peptide that elicits a targeted immune response against HER2*neu*-expressing cancers. Below is an image of a cell surface showing therapeutically relevant cell surface proteins in cancer. Breast cancers and other solid tumors with elevated expression of HER2/*neu* protein are highly aggressive with an increased disease recurrence and a worse prognosis.



Mechanism of Action

As shown below, following GP2 immunotherapy, CD8+ cytotoxic T lymphocytes ("CTLs") recognize and destroy HER2/*neu*-expressing cancer cells. GP2 is administered in combination with an FDA-approved immunoadjuvant GM-CSF, which stimulates the proliferation of antigen presenting cells. Preclinical studies have shown that T cells sensitized against the GP2 peptide demonstrate significant recognition of HER2/*neu*-expressing tumors. Both ovarian and breast cancer-specific CTLs recognize GP2, which is widely expressed in HER2/*neu*-expressing tumors and is capable of inducing tumor-specific CTL populations in vitro.



Corporate Strategy

Our corporate strategy includes advancing GP2 into a Phase III clinical trial in the U.S. with favorable regulatory designations and pursuing a European and global clinical trial strategy to support GP2 registration outside of the U.S. We are considering various options to fund the Phase III clinical trial including financing and/or strategic transactions. Our strategy also includes, among other things, building a commercialization team, pursuing additional funding after this offering, and pursuing strategic collaborations to support the future global marketing and sales of GP2. A long term global and regional licensing process has been initiated and will continue as the Phase III trial commences.

Pipeline Strategy — Including GP2 In Other HER2/neu-Expressing Cancers

We are developing follow-on indications for GP2 by designing and planning additional clinical trials to expand the breast cancer patient population and to pursue additional HER2/*neu*-expressing cancers. Pending receipt of sufficient capital, the planned Phase III clinical trial can be supplemented with the following pipeline investments:

- The efficacy of GP2-GMCSF-Herceptin can be explored in (1) other HLA patients in the same HER2/*neu* 3+ breast cancer patient population, (2) breast cancer patients who are low to intermediate expressors of HER2/*neu* (1-2+) and who comprise two-thirds of the triple negative market, or (3) other HER2/*neu*-expressing cancers including, but not limited to, ovarian, gastrointestinal, and colon cancers.
- We may acquire a preclinical platform that can be quickly advanced into IND-enabling GMP manufacturing and GLP toxicology studies followed by initial human clinical trials.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware of before making an investment decision. These risks are discussed more fully in the "*Risk Factors*" section of this prospectus immediately following this prospectus summary. Some of these risks include the following:

- We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We currently have no source of revenues. We may never generate revenues or achieve profitability.

- We expect to continue to incur significant operating and non-operating expenses, which may make it difficult for us to secure sufficient financing and may lead to uncertainty about our ability to continue as a going concern.
- We are dependent on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed, and if we fail to meet our obligations under our current or future license agreements, we may lose the ability to develop our product candidate.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We are currently a clinical-stage biopharmaceutical company with a product candidate in clinical development. If we are unable to successfully develop and commercialize our product candidate or experience significant delays in doing so, our business may be materially harmed.
- Our success relies on third-party suppliers and manufacturers. Any failure by such third parties, including, but not limited to, failure to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market our product candidate, and our business could be substantially harmed.
- Our future success is dependent on the regulatory approval of our product candidate.
- Our business may be adversely affected by the ongoing coronavirus pandemic.

Corporate Information

We were incorporated as a Delaware corporation on August 29, 2006 under the name Norwell, Inc. On March 2, 2018, we changed our name to Greenwich LifeSciences, Inc. Our principal executive offices are located at 3992 Bluebonnet Dr., Building 14, Stafford, TX 77477 and our telephone number is (832) 819-3232. Our website address is *www.greenwichlifesciences.com*. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenues during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act ("JOBS Act") enacted in 2012. As an emerging growth company, we expect to take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act");
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we intend to take advantage of an extended transition period for complying with new or revised accounting standards as permitted by the JOBS Act.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (ii) scaled executive compensation disclosures; and (iii) the requirement to provide only two years of audited financial statements, instead of three years.

THE OFFERING

Common stock offered by us	1,000,000 Shares
Common stock to be outstanding immediately after this offering	11,593,555 shares (11,743,555 shares if the underwriters exercise their option in full)
Option to purchase additional shares	The underwriters have an option for a period of 45 days to purchase up to an additional 150,000 shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $6,752,925, or approximately $7,856,925 if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of $8.00 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for clinical trials, manufacturing our product candidate, retention of contract research organizations and for working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products, however, we have no current commitments or obligations to do so. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.
Underwriters' warrants	Upon the closing of this offering, we have agreed to issue to Aegis Capital Corp., as representative of the underwriters, warrants that will be exercisable for the period commencing six months from the effective date of this offering and expiring five years from the effective date of the offering, entitling the representative to purchase 8% of the number of shares of common stock sold in this offering (excluding shares of common stock sold to cover over-allotments, if any). The registration statement of which this prospectus is a part also covers the underwriters' warrants and the common shares issuable upon the exercise thereof. For additional information regarding our arrangement with the underwriters, please see "Underwriting."
Lock-up agreements	We and our executive officers and directors have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for 180 days after the date of this prospectus. For additional information regarding our arrangement with the underwriters, please see "Underwriting."
Risk factors	See "Risk Factors" on page 10 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Capital Market symbol	"GLSI"

The number of shares of our common stock to be outstanding after this offering is based on 8,613,190 shares of our common stock outstanding as of June 15, 2020, and excludes as of that date:

- 1,520,937 shares of common stock issuable upon conversion of 1,520,937shares of our Series A Preferred Stock outstanding calculated by dividing the Original Series A Price by the Series A Conversion Price based upon an assumed initial public offering price of $8.00 per share, the midpoint of the range set forth on the cover page of this prospectus. The "Original Series A Price" means $0.267 per share, subject to adjustment. The "Series A Conversion Price" means $0.267 per share, subject to adjustment;

- 129,267 shares of common stock issuable upon conversion of 129,267 shares of our Series B Preferred Stock outstanding calculated by dividing the Original Series B Price by the Series B Conversion Price based upon an assumed initial public offering price of $8.00 per share, the midpoint of the range set forth on the cover page of this prospectus. The "Original Series B Price" means $1.335 per share, subject to adjustment. The "Series B Conversion Price" means $1.335 per share, subject to adjustment;
- 66,575 shares of common stock issuable upon conversion of 66,575 shares of our Series C Preferred Stock outstanding calculated by dividing the Original Series C Price by the Series C Conversion Price based upon an assumed initial public offering price of $8.00 per share, the midpoint of the range set forth on the cover page of this prospectus. The "Original Series C Price" means $2.67 per share, subject to adjustment. The "Series C Conversion Price" means $2.67 per share, subject to adjustment;
- 263,586 shares of common stock issuable upon conversion of 263,586 shares of our Series D Preferred Stock outstanding calculated by dividing the Original Series D Price by the Series D Conversion Price based upon an assumed initial public offering price of $8.00 per share, the midpoint of the range set forth on the cover page of this prospectus. The "Original Series D Price" means $5.34 per share, subject to adjustment. The "Series D Conversion Price" means $5.34 per share, subject to adjustment;
- 675,529 shares of common stock subject to future vesting issued to members of management and directors;
- 1,498,128 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan.
- 80,000 shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters as part of this offering at an exercise price of $10.00 (assuming an initial public offering price of $8.00 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

Except as otherwise indicated herein, all information in this prospectus assumes or gives effect to:

- a 1-for-2.67 stock split of our common and preferred stock effected on June22, 2020 pursuant to which (i) every 2.67 shares of outstanding common stock was decreased to one share of common stock and (ii) the conversion ratio for each share of outstanding preferred stock into common stock was proportionately reduced on a 1-for-2.67 basis (the "Reverse Stock Split"). No fractional shares will be issued as a result of the Reverse Stock Split. Any fractional shares resulting from the Reverse Stock Split shall be rounded up to the nearest whole share;
- the conversion of all of outstanding Series A Preferred Stock into an aggregate of 1,520,937 shares of our common stock, the conversion of all of outstanding Series B Preferred Stock into an aggregate of 129,267 shares of our common stock, the conversion of all of outstanding Series C Preferred Stock into an aggregate of 66,575 shares of our common stock and the conversion of all of outstanding Series D Preferred Stock into an aggregate of 263,586 shares of our common stock upon the closing of this offering; and
- no exercise by the underwriters of their option to purchase an additional 150,000 shares of common stock.

Summary Financial Data

The following tables set forth our summary financial data as of the dates and for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the three months ended March 31, 2020 and 2019 and the summary balance sheet data as of March 31, 2020 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the three months ended December 31, 2020 are not necessarily indicative of the results that may be expected for the full fiscal year.

Statement of Operations Data:

(in thousands, except share and per share data)

	Years Ended December 31,		Three Months Ended March 31, (unaudited)	
	2019	**2018**	**2020**	**2019**
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	2,606	1,270	150	126
General and administrative	819	420	95	22
Total operating expenses	3,425	1,690	245	148
Net loss	$ (3,425)	$ (1,690)	$ (245)	$ (148)
Net loss per common share – basic and diluted[(1)]	$ (1.52)	$ (8.32)	$ (0.03)	$ (0.73)
Weighted average common shares outstanding – basic and diluted[(1)]	2,257,979	202,996	8,496,834	202,996

(1) See Note 3 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

Balance Sheet Data:

(in thousands)

	March 31, 2020 (unaudited)		
	Actual	**Pro Forma[(1)]**	**Pro Forma, As Adjusted[(2)(3)]**
Cash	$ 7	$ 7	$ 6,760
Working capital deficit	(1,440)	(1,440)	5,313
Total assets	26	26	6,779
Total liabilities	1,447	1,447	1,447
Accumulated deficit	(27,459)	(27,633)	(28,880)
Total stockholders' equity (deficit)	(1,421)	(1,421)	5,332

(1) On a pro forma basis to reflect the issuance of an aggregate of 77,571 shares of common stock in April, May, and June 2020 in consideration for services rendered.

(2) On a pro forma as adjusted basis to give further effect to our (i) issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $8.00 per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the conversion of all outstanding shares of preferred stock into an aggregate of 1,980,365 shares of common stock upon closing of the offering.

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $8.00 per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by approximately $920,000, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 500,000 shares in the number of shares offered by us at the assumed initial public offering price per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by approximately $3,680,000.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this prospectus, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Financial Position and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharmaceutical company focused on the development of our novel cancer immunotherapy GP2, for breast cancer and potentially for a broad range of other HER2/*neu*-expressing cancers. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from collaboration and licensing agreements or product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses since our inception. For the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, we reported a net loss of $0.2 million, $3.4 million and $1.7 million, respectively. As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of $27.5million and $27.2 million, respectively.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidate and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we:

- conduct clinical trials of our lead product candidate, GP2;
- in-license or acquire the rights to, and pursue development of, other products, product candidates or technologies;
- hire additional clinical, manufacturing, quality control, quality assurance and scientific personnel;
- seek marketing approval for any product candidates that successfully complete clinical trials;
- develop our outsourced manufacturing and commercial activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidate. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our existing cash as of March 31, 2020 together with proceeds from this offering will enable us to fund our operating expenses through and capital expenditure requirements for twelve months from the date of this prospectus; however, our existing cash will not be sufficient to complete development and obtain regulatory approval for our product candidate, and we will need to raise significant additional capital to help us do so. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our product candidate and the advancement and expansion of our preclinical research pipeline. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any.

We believe that it may cost approximately $12 million to $15 million to complete an interim analysis of the safety and efficacy of our Phase III trial. Furthermore, the total cost to complete an interim analysis and file a BLA application for drug approval in the U.S. could exceed $16 million, and the total cost to complete our Phase III trial as planned could exceed $30 million; however, we believe that we have budget flexibility based upon the amount of proceeds raised from this offering as well as subsequent financings and other sources of capital with respect to the design of the Phase III clinical trial. We believe that we may be able to alter the cost of our Phase III clinical trial by adjusting the enrollment rate, the number of patients, and/or the number of immunological assays. While our budget for such Phase III trial may be flexible, our ability to reduce or modify costs may be adversely effected by, among other things, unexpected or higher costs associated with the trial, time required to complete the trial and other factors that may be beyond our control. Our budgets and future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned development programs for our product candidate, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our product candidate;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidate if our clinical trials are successful;
- the cost of commercialization activities for our product candidate, if our product candidate is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidate for clinical trials in preparation for regulatory approval, including the cost and timing of process development, manufacturing scale-up and validation activities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs in defending and resolving future derivative and securities class action litigation;
- our operating expenses; and
- the emergence of competing technologies or other adverse market developments.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidate or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidate.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of the Company. We may not be able to identify or consummate any suitable strategic alternatives.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of the Company. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into

any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidate on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets, including our intellectual property. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidate or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may need to curtail or cease our operations.

There is substantial doubt about our ability to continue as a going concern.

As of March 31, 2020 and December 31, 2019, we had cash of $6,835. In addition, we had current liabilities of approximately $1.4 million as of March 31, 2020 and December 31, 2019. We expect our existing cash as of March 31, 2020 together with proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements for twelve months from the date of this prospectus. In the event that we are unable to obtain additional financing, we may be unable to continue as a going concern. There is no guarantee that we will be able to secure additional financing, including in connection with this offering. Changes in our operating plans, our existing and anticipated working capital needs, costs related to legal proceedings we might become subject to in the future, the acceleration or modification of our development activities, any near-term or future expansion plans, increased expenses, potential acquisitions or other events may further affect our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2019 and 2018 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our securityholders may lose some or all of their investment in us.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidate, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our current product candidate, GP2, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit either Biologics License Applications, or BLAs, or New Drug Applications, or NDAs, to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;

- set commercially viable prices for our product, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and/or build our own manufacturing facility and ensure adequate, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our product candidate;
- develop commercial quantities of our product candidate, once approved, at acceptable cost levels; obtain additional funding, if required to develop and commercialize our product candidate;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose to commercialize on our own;
- achieve market acceptance of our product;
- attract, hire and retain qualified personnel; and
- protect our rights in our intellectual property portfolio.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

The Tax Cuts and Jobs Act could adversely affect our business and financial condition.

H.R. 1, "An Act to provide for reconciliation pursuant to title II and V of the concurrent resolution on the budget for fiscal year 2018," informally entitled the Tax Cuts and Jobs Act ("Tax Act") enacted on December 22, 2017, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a single rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), providing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had federal net operating loss, or NOLs, carryforwards of approximately $3.8 million. Our NOLs generated in tax years ending on or prior to December31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

Risks Related to the Development and Regulatory Approval of Our Product Candidate

Clinical-stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which may entail substantial risk.

We are a clinical-stage biopharmaceutical company with a product candidate in clinical development. The success of our product candidate will depend on several factors, including the following:

- designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND-enabling studies, for our product candidate or product candidates we may, in the future, in-license or acquire;
- designing, conducting and completing clinical trials for our product candidate with positive results;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidate;
- making arrangements with third-party manufacturers, receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product;
- manufacturing our product candidate at an acceptable cost;
- effectively launching commercial sales of our product candidate, if approved, whether alone or in collaboration with others;
- achieving acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our product candidate is approved, obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidate;
- complying with all applicable regulatory requirements, including FDA current Good Clinical Practices ("GCP"), current Good Manufacturing Practices ("cGMP"), and standards, rules and regulations governing promotional and other marketing activities;
- maintaining a continued acceptable safety profile of the product during development and following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidate, which could materially harm our business.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidate is being studied which could delay or prevent the start of clinical trials for our product candidate.

Identifying and qualifying patients to participate in clinical trials of our product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidate, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidate will most likely be delayed.

Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- willingness of physicians to participate in our planned clinical trials;
- severity of the disease under investigation;
- proximity of patients to clinical sites;
- patients who do not complete the trials for personal reasons; and
- issues with CROs and/or with other vendors that handle our clinical trials.

We may not be able to initiate or continue to support clinical trials of our product candidate for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidate may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidate, the commercial prospects of our product candidate could be harmed, and our ability to generate product revenue from any of our product candidate could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidate in clinical trials, and any other product candidates that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials.

Despite the results reported in earlier preclinical studies or clinical trials for our product candidate, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidate for a particular indication, in any particular jurisdiction. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidate may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market our current product candidate or any future product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

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

We may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical trials of our product candidate on hold in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third-party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;

- delay or failure in adding new trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, the IRB or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

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

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

We may conduct future studies 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;
- 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 current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials by the FDA or other comparable foreign regulatory authorities; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human subjects. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market our current product candidate or any product candidates we may pursue, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or any future product candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if our product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such product;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidate, if approved.

Our product development program may not uncover all possible adverse events that patients who take our product candidate may experience. The number of subjects exposed to our product candidate and the average exposure time in the clinical development program may be inadequate to detect rare adverse events or chance findings that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our product candidate will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to our product candidate. If such safety problems occur or are identified after our product candidate reaches the market, the FDA may require that we amend the labeling of the product or recall the product, or may even withdraw approval for the product.

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. 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.

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 study 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.

Our current product candidate and future product candidates could fail to receive regulatory approval from the FDA.

We have not obtained regulatory approval for our product candidate and it is possible that our existing product candidate or any future product candidates will not obtain regulatory approval, for many reasons, including:

- disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidate to support the submission and filing of a BLA, NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval or additional studies, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve our current product candidate and any future product candidates we may pursue for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we are unable to obtain regulatory approval for our product candidate in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidate from being marketed 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 and 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 and this could materially adversely affect our business, results of operations and financial condition.

Even if our current candidate receive regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our product candidate, that approval would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our CMOs and CROs for any post-approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, GCP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the U.S. is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. is heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our product for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

Risks Related to Our Manufacturing

We have limited to no manufacturing, sales, marketing or distribution capability and must rely upon third parties for such.

We currently have purchase orders with various third-party manufacturing facilities for production of our product candidate for research and development and testing purposes. We depend on these manufacturers to meet our deadlines, quality standards and specifications. Our reliance on third parties for the manufacture of our active pharmaceutical ingredient and drug product and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical drug supplies of our product candidate, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail.

The active pharmaceutical ingredient for our product candidate is currently sourced from Polypeptide Laboratories located in San Diego, California. We believe this single source is currently capable of supplying all anticipated needs of our proposed clinical studies, as well as initial commercial introduction. We will be developing a source or sources for drug product manufacturing. If we are able to commercialize our product in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP. Once the nature and scope of additional indications and their commensurate drug product demands are established, we will seek secondary suppliers of both the active pharmaceutical ingredient and drug product for our product candidate, but we cannot assure that such secondary suppliers will be found on terms acceptable to us, or at all.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidate.

We and our CMOs will need to conduct significant development work for our product candidate for each target indication for studies, trials and commercial launch readiness. Developing commercially viable manufacturing processes is a difficult, expensive and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidate will be made could be adversely affected by earthquakes and other natural disasters, medical pandemics, equipment failures, labor shortages, power failures, and numerous other factors.

Additionally, the process of manufacturing our product candidate is complex, highly regulated and subject to several risks, including but not limited to:

- product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error;
- reduced production yields, product defects, and other supply disruptions due to deviations, even minor, from normal manufacturing and distribution processes;

- unexpected product defects; and
- microbial, viral, or other contaminations in our product candidate or in the manufacturing facilities in which our product candidate is made, which may result in the closure of such manufacturing facilities for an extended period of time to allow for the investigation and remediation of the contamination.

Any adverse developments affecting manufacturing operations for our product candidate may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product, which could delay the development of our product candidate. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidate could damage our reputation and the reputation of our product among physicians, healthcare payors, patients or the medical community, and cancer treatment centers, which could adversely affect our ability to operate our business and our results of operations.

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, thus jeopardizing the completion of the trials.

GP2 is administered in combination with GM-CSF which is available in both liquid and lyophilized forms exclusively from one manufacturer. 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. 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.

If any of our CMOs' clinical manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

If our CMOs' manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to another CMO. Even if we could transfer manufacturing to another CMO, the shift would likely be expensive and time-consuming, particularly because the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales.

Although we do not currently maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses, any insurance coverage we obtain in the future may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidate if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties and Our License Agreements

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs or other key third-party vendors, we may not be able to obtain regulatory approval for or commercialize our current or future product candidates on a timely basis, if at all.

Our internal capacity for clinical trial execution and management is limited and therefore we rely heavily on third parties. We have relied upon and plan to continue to rely upon third-party CROs, vendors and contractors to monitor and manage data for our ongoing preclinical and clinical programs. For example, our collaborating investigators along with their clinical and clinical operations teams may manage the conduct of any future clinical trials for GP2 as well as perform the analysis, publication and presentation of data and results related to this program.

We plan to rely on CROs and other third-party vendors for all currently contemplated clinical studies. We rely on these parties for the execution of our preclinical studies and clinical trials, including the proper and timely conduct

of our clinical trials, and we control only some aspects of their activities. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results or data in a timely manner or may fail to perform at all.

While we may have agreements governing the commitments of our third-party vendor services, we will have limited influence over their actual performance. Nevertheless, we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs will not relieve us of our regulatory responsibilities.

If our Company, or any of our partners or CROs, fail to comply with applicable regulations and good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our regulatory applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable requirements. In addition, our clinical trials must be conducted with product produced under cGMP and other requirements. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *clinicaltrials.gov*, within a specified timeframe. Failure to comply also would violate federal requirements in the U.S. and could result in other penalties, which would delay the regulatory approval process and result in adverse publicity.

Our CROs, third-party vendors and contractors are not and will not be our employees, and except for remedies available to us under our agreements with such CROs, third-party vendors and contractors, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. They may also have relationships with other entities, some of which may be our competitors. If CROs, third-party vendors and contractors do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our current or future product candidates. CRO, vendor or contractor errors could cause our results of operations and the commercial prospects for our current or future product candidates to be harmed, our costs to increase and our ability to generate revenues to be delayed.

In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though, once engaged, we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are dependent on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed, and if we fail to meet our obligations under our license agreements, we may lose the ability to develop our product candidate.

We currently are dependent on a license from HJF for technologies relating to our product candidate. The license imposes, and any future licenses we enter into are likely to impose, various development, funding, royalty, diligence, sublicensing, insurance and other obligations on us. If our license with respect to any of these technologies is terminated for any reason, the development of the products contemplated by the licenses would be delayed, or suspended altogether, while we seek to license similar technology or develop new non-infringing technology which could have a material adverse effect on our business.

We may not realize the benefits of our strategic alliances that we may form in the future.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we

may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for or current product candidate or any future product candidates and programs because our research and development pipeline may be insufficient, our current product candidate and future product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view such product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances agreements related to our current product candidate or future product candidates could also delay the development and commercialization of such product candidates and reduce their competitiveness even if they reach the market.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials even after we sell or otherwise dispose of the products. In some cases, these hazardous materials and various wastes resulting from their use will be stored at our contractors or manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause injury to our employees and others, environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we expect that the safety procedures utilized by our third-party contractors and manufacturers for handling and disposing of these materials will generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this will be the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and any future property and casualty, and general liability insurance policies may exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize our product candidate.

We expect to depend on collaborators, partners, licensees, CROs and other third parties to formulate our product candidate, to manufacture our product candidate, and to conduct clinical trials for our product candidate. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidate. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidate. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our product candidate, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

In addition, we may receive notices from third parties from time to time alleging that our technology or product candidate infringes upon the intellectual property rights of those third parties. Any assertion by third parties that our activities or product candidate infringes upon the intellectual property rights of third parties may adversely affect our ability to secure strategic partners or licensees for our technology or product candidate or our ability to secure or maintain manufacturers for our compounds.

Risks Related to Our Intellectual Property

We rely on an exclusive license granted to us by HJF with respect to GP2, and if HJF does not adequately defend such license, our business may be harmed.

We have been granted an exclusive license to GP2, our product candidate, from HJF. The GP2 patent rights were assigned to HJF by certain third parties including the Uniformed Services University of the Health Sciences. We rely on HJF to maintain the patents already issued with respect to GP2, to continue to pursue patent applications pending in certain countries with respect to GP2, and otherwise protect the intellectual property covered by our exclusive license agreement. We have limited control over the activities of HJF or over any other intellectual property that may be related to GP2. For example, we cannot be certain that activities by HJF have been or will be conducted in compliance with applicable laws and regulations and/or any agreements between HJF and the third party assignors. We have no control or input over whether, and in what manner, HJF may enforce or defend the patents against a third-party. HJF may enforce or defend the patent less vigorously than if we had enforced or defended the patents ourselves. Further, HJF may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, HJF may not enforce the patents against a competitor of ours who is not a direct competitor of HJF. If our in-licensed intellectual property is found to be invalid or unenforceable, then HJF may not be able to enforce the patents against a competitor of ours. If we fail to meet our obligations under our exclusive license agreement with HJF, then HJF may terminate such agreement. Although we may choose to terminate our license agreement with HJF, doing so would allow a third party to seek and obtain an exclusive license to GP2. If a third party obtains an exclusive license to intellectual property with respect to GP2, then the third party may seek to enforce the intellectual property against us which may have a material adverse effect on our business.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidate, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current product candidate and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. As of the date of this prospectus, we only have licensed rights from HJF to certain issued patents as well as patent applications which are currently pending in certain countries with respect to GP2. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidate is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidate, but that are not covered by the claims of our licensed patents;
- HJF might not have been the first to make the inventions covered by its pending patent applications;

- we or HJF might not have been the first to file patent applications for these inventions;
- HJF'spending patent applications may not result in issued patents;
- the claims of HJF's issued patents or patent applications when issued may not cover our product or product candidate;
- any patents that we obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our product candidate.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidate. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidate, which could harm our business significantly.

We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

If we choose to commence a proceeding or litigation to prevent another party from infringing HJF's patents, that party will have the right to ask the examiner or court to rule that such patents are invalid or should not be enforced against them. There is a risk that the examiner or court will decide that HJF's patents are not valid and that HJF does not have the right to stop the other party from using the related inventions. There is also the risk that, even if the validity of such patents is upheld, the examiner or court will refuse to stop the other party on the ground that such other party's

activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office (the "USPTO") in granting patents over the past 20 years, which may decrease the likelihood that we or HJF will be able to obtain patents and increase the likelihood of challenge to any patents we obtain or license. Any proceedings or litigation to enforce our intellectual property rights or defend ourselves against claims of infringement of third-party intellectual property rights could be costly and divert the attention of managerial and scientific personnel, regardless of whether such litigation is ultimately resolved in our favor. We may not have sufficient resources to bring these actions to a successful conclusion. Moreover, if we are unable to successfully defend against claims that we have infringed the intellectual property rights of others, we may be prevented from using certain intellectual property and may be liable for damages, which in turn could materially adversely affect our business, financial condition or results of operations.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our product candidate, or manufacture or use of our product candidate, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidate. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidate or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidate to market and be precluded from manufacturing or selling our product candidate.

We cannot be certain that others have not filed patent applications for technology covered by HJF's pending applications, or that HJF the first to invent the technology, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over HJF's patent applications, which could require us to obtain rights to issued patents covering such technologies. If another party has filed U.S. patent applications on inventions similar to HJF that claims priority to any applications filed prior to the priority dates of HJF's applications, HJF may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. It is possible that such efforts would be unsuccessful if, unbeknownst to HJF, the other party had independently arrived at

the same or similar inventions prior to HFJ's inventions, resulting in a loss of HFJ's U.S. patent position with respect to such inventions which could in turn have a material adverse effect on our operations. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us or the third parties from whom we license intellectual property because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Furthermore, any license agreements we enter into in the future may require us to notify, and in some cases license back to the licensor, certain additional proprietary information or intellectual property that we developed using the rights licensed to us under these agreements. Any such licenses back to the licensor could allow our licensors to use that proprietary information or intellectual property in a manner that could harm our business. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our product candidate from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our product candidate or future product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;

- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidate in the future. There can be no assurance that we will be able to successfully defend patents we own or license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S.; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act, AIA or Leahy -Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that the patents of our licensor can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the USPTO, courts and foreign government patent agencies, and HJF's patent protection could be reduced or eliminated for non-compliance with these requirements which may have a material adverse effect on our business.

Risks Related to Commercialization of Our Current Product Candidate and Future Product Candidates

Our commercial success depends upon attaining significant market acceptance of our current product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.

Even if we obtain regulatory approval for our current product candidate or any future product candidates, the products may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including cancer treatment centers. Market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major cancer treatment centers and patients of the drug as a safe and effective treatment;
- the adoption of novel immunotherapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including our use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our product as well as competitive products;

- the development of manufacturing and distribution processes for commercial scale manufacturing for our current product candidate and any future product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If our current product and any future product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or cancer treatment centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our current product candidate or any future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from third-party payors, including government health administration authorities, private health insurers and other organizations.

Third-party payors determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefit and value in specific patient populations before covering our product for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. No uniform policy for coverage and reimbursement exists in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved product that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize our product and overall financial condition.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the U.S. and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to

sell our product profitably. In particular, in 2010, the Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current U.S. administration to repeal or repeal and replace certain aspects of the ACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as a part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. Until there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidate, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidate, if approved.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices.

In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Risks Related to Healthcare Compliance Regulations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which

require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;

- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to our Business Operations

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidate. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our current product candidate, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidate could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate. The biotechnology industry, including the cancer immunotherapy market, is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the U.S. and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology or may introduce products to market earlier than our product or on a more cost-effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our product candidate could result in our having limited prospects for establishing market share or generating revenue.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or potentially advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our current product candidate. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidate obsolete or noncompetitive before we can recover the expenses of development and commercialization.

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus (COVID-19) has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of the coronavirus, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If either any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

As a result of the shelter-in-place order and other mandated local travel restrictions, our employees conducting research and development or manufacturing activities may not be able to access their laboratory or manufacturing space which may result in our core activities being significantly limited or curtailed, possibly for an extended period of time.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we may contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Our internal computer systems, and those of our CROs, our CMOs, and other business vendors on which we may rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of June 15, 2020, we had no full-time employees and 3 part-time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel, including Snehal Patel, our Chief Executive Officer and member of our board of directors. The loss of Mr. Patel's services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Owning our Common Stock and this Offering

An active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the initial public offering price.

Prior to the consummation of this offering, there has been no public market for our common stock. An active trading market for shares of our common stock may never develop or be sustained following this offering. If an active trading market does not develop, you may have difficulty selling your shares of common stock at an attractive price, or at all. The price for our common stock in this offering will be determined by negotiations between us and the underwriters, and it may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell your common stock at or above the initial public offering price or at any other price or at the time that you would like to sell. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using our common stock as consideration.

We are registering shares of common stock to certain stockholders concurrently with the primary offering and while these stockholders have expressed an intent not to sell stock concurrently with the primary offering, if they did do so, such sales might affect the price, demand, and liquidity of our common stock.

We are registering shares of common stock to certain security holders concurrently with the primary offering which include the potential resale by certain selling stockholders of an aggregate amount up to 1,685,394 shares of our common stock. Sales by these selling stockholders may reduce the price of our common stock, demand for the shares sold in the offering and, as a result, the liquidity of your investment.

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this prospectus, are:

- sale of our common stock by our stockholders, executives, and directors and our stockholders whose shares are being registered in this offering;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidate or any future clinical trials we may conduct;
- changes in the development status of our product candidate;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidate;
- unanticipated safety concerns related to the use of our product candidate;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;

- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this initial public offering, including for any of the currently intended purposes described in the section entitled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from this offering in ways that ultimately increase the value of any investment in our securities or enhance stockholder value. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional products or licenses, commercialize our product, or continue our operations.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the current COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock after the closing of this offering, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

Following this offering, our directors, executive officers and principal stockholders, and their respective affiliates, will beneficially own approximately 72% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

You will incur immediate dilution as a result of this offering.

If you purchase common stock in this offering, you will pay more for your shares than the net tangible book value of your shares. As a result, you will incur immediate dilution of $7.54 per share, representing the difference between the assumed initial public offering price of $8.00 per share (the midpoint of the range on the cover of this prospectus) and our estimated pro forma net tangible book value per share as of March 31, 2020 of $0.46. Accordingly, should we be liquidated at our book value, you would not receive the full amount of your investment.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the 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 cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock

less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." 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 this 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.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

There is no guarantee that our common stock will be listed on Nasdaq.

We have applied to have our shares of common stock listed on The Nasdaq Capital Market. Upon completion of this offering, we believe that we will satisfy the listing requirements and expect that our common stock will be listed on The Nasdaq Capital Market. Such listing, however, is not guaranteed. If the application is not approved, we may seek to have our common stock quoted on the OTCQB maintained by the OTC Markets Group, Inc. Even if such listing is approved, there can be no assurance any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you purchase in this offering if you desire or need to sell them.

Our second amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our second amended and restated bylaws (the "Amended and Restated Bylaws"), to be effective upon completion of this offering, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, to be effective upon completion of this offering, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Upon consummation of this offering, we will be authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. As of June 15, 2020, we have designated 4,200,000 shares of preferred stock as Series A Preferred Stock, of which 1,520,937 are issued and outstanding; 390,000 shares of preferred stock as Series B Preferred Stock, of which 129,267 are issued and outstanding; 205,000 shares of preferred stock as Series C Preferred Stock, of which 66,575 are issued and outstanding; and 2,000,000 shares of preferred stock as Series D Preferred Stock, of which 263,586 are issued and outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we will incur significant additional legal, accounting and other expenses that we did not incur as a privately company. The obligations of being a public company in the U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

Our Amended and Restated Bylaws to be effective upon completion of this offering provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or employees.

Our Amended and Restated Bylaws to be effective upon completion of this offering provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL") or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws to be effective upon completion of this offering, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Bylaws to be effective upon completion of this offering contain a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in either our Amended and Restated Bylaws to be effective upon completion of this offering to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

If we fail to comply with the rules under Sarbanes-Oxley related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. In some cases, you can identify these forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "depends," "estimate," "expects," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidate;
- the ultimate impact of the current coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of preclinical and clinical trials indicate our current product candidate or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current product candidate;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidate;
- market acceptance of our product candidate, the size and growth of the potential markets for our current product candidate and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, 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 we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

INDUSTRY AND MARKET DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty, including those discussed in "Risk Factors." We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $6.8 million, based on an assumed initial public offering price of $8.00 per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $7.9 million.

We intend to use the net proceeds to fund our planned clinical trials, manufacturing and for general corporate purposes, including working capital. We intend to use the first $3.4 million of net proceeds from this offering in the following order:

- Approximately $0.6 million to complete the manufacturing of our product candidate, GP2;
- Approximately $2.1 million to enroll and treat the first 50 to 100 patients in our Phase III clinical trial; and
- Approximately $0.7 million for working capital and other general corporate purposes.

Any additional capital that we raise pursuant to this offering will be used for the enrollment of additional patients in our Phase III clinical trial, for the retention of CROs to conduct clinical trials, and for additional working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products, however, we have no current commitments or obligations to do so.

We believe that it may cost approximately $12 million to $15 to complete an interim analysis of the safety and efficacy of our Phase III trial. If we are unable to raise sufficient funds for our Phase III trial as a result of this offering, we believe that we may be able to raise additional funds pursuant to subsequent financings or from the proceeds of potential strategic transactions from the out-licensing of marketing rights to GP2. We have flexibility based upon the amount of proceeds raised from this offering as well as subsequent financings and other sources of capital with respect to the design of the Phase III clinical trial which we believe that we may be able to alter by adjusting the enrollment rate, the number of patients, and/or the number of immunological assays. We believe that we can also reduce costs associated with our Phase III trial by managing the clinical trial with internal staff instead of using CROs and by further reducing management and staff compensation and overhead expenses, as necessary.

A $1.00 increase or decrease in the assumed initial public offering price of $8.00 per share would increase or decrease the net proceeds from this offering by approximately $0.92 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

This expected use of the net proceeds from this offering and our existing cash represents our intentions based upon our current plans, financial condition and business conditions. Predicting the cost necessary to develop a product candidate can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidate and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and our existing cash.

In the ordinary course of our business, we expect to from time to time evaluate the acquisition of, investment in or in-license of complementary products, technologies or businesses, and we could use a portion of the net proceeds from this offering for such activities. We currently do not have any agreements, arrangements or commitments with respect to any potential acquisition, investment or license.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and government securities.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March31, 2020:

- on an actual basis;
- on a pro forma basis to reflect the issuance of an aggregate of 77,571 shares of common stock in April, May, and June 2020 in consideration for services rendered; and
- on a pro forma as adjusted basis to give further effect to (i) our issuance and sale of 1,000,000 shares of our common stock included in the shares of common stock being sold in this offering at an assumed initial public offering price of $8.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and our estimated offering expenses and (ii) the conversion of all outstanding shares of preferred stock into an aggregate of 1,980,365 shares of common stock upon closing of the offering.

(in thousands, except share and per share data)	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma, As Adjusted[1] (unaudited)
Cash	$ 7	$ 7	$ 6,760
Short term notes payable to related parties	635	635	635
Stockholders' deficit:			
Preferred stock, par value $0.001 per share; 6,795,000 shares authorized, 1,980,365 issued and outstanding, actual; 6,795,000 shares authorized, 1,980,365 issued and outstanding, pro forma; 10,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	2	2	–
Common stock, par value $0.001 per share; 100,000,000 shares authorized, 8,535,619 shares issued and outstanding, actual; 100,000,000 shares authorized, 8,613,190 shares issued and outstanding, pro forma; 100,000,000 shares authorized, 11,593,555 shares issued and outstanding, pro forma as adjusted	9	9	12
Additional paid-in capital	26,027	26,201	34,200
Accumulated deficit	(27,459)	(27,633)	(28,880)
Total stockholders' equity (deficit)	(1,421)	(1,421)	5,332
Total capitalization	$ (1,421)	$ (1,421)	$ 5,332

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $8.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by $0.92 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase (decrease) of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by $3.68 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

The number of shares of our common stock to be outstanding after this offering is based on 8,535,619 shares of our common stock outstanding as of March 31, 2020, assumes no exercise by the underwriters of their over-allotment option and excludes:

- 753,100 shares of common stock subject to future vesting issued to members of management and directors;
- 1,498,128 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan; and
- 80,000 shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters as part of this offering at an exercise price of $10.00 (assuming an initial public offering price of $8.00 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of March 31, 2020 we had a historical net tangible book value (deficit) of $(1,440,051), or $(0.17) per share of common stock, based on 8,535,619 shares of common stock outstanding at March31, 2020. Our historical net tangible book value per share is the amount of our total tangible assets less our total liabilities at March 31, 2020, divided by the number of shares of common stock outstanding at March 31, 2020.

After giving effect to the issuance of an aggregate of 77,571 shares of common stock in April, May, and June 2020 in consideration for services rendered, our pro forma net tangible book value (deficit) as of March 31, 2020 was $(1,440,051), or $(0.17) per share of common stock.

After giving further effect to (i) the sale of 1,000,000 shares of common stock in this offering at an assumed initial public offering price of $8.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the conversion of all outstanding shares of preferred stock into an aggregate of 1,980,365 shares of common stock upon closing of the offering, our pro forma as adjusted net tangible book value at March 31, 2020 would have been $5.3 million, or $0.46 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $0.60 per share to existing stockholders and immediate dilution of $7.54 per share to new investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$ 8.00
Pro forma net tangible book value per share as of March 31, 2020	$ (0.14)	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors in this offering	0.60	
Pro forma as adjusted net tangible book value per share immediately after this offering		0.46
Dilution per share to new investors in this offering		$ 7.54

A $1.00 increase (decrease) in the assumed initial public offering price of $8.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value after this offering by $0.08 per share and the dilution to new investors purchasing common stock in this offering by $0.92 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and commissions. An increase of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value after this offering by $0.29 per share and decrease the dilution to new investors purchasing common stock in this offering by $0.29 per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. A decrease of 500,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value after this offering by $0.31 per share and increase the dilution to new investors purchasing common stock in this offering by $0.31 per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be $0.55 per share. This represents an increase in pro forma as adjusted net tangible book value of $0.69 per share to existing stockholders and dilution in pro forma as adjusted net tangible book value of $7.45 per share to new investors.

The number of shares of our common stock to be outstanding after this offering is based on 8,535,619 shares of our common stock outstanding as of March 31, 2020, assumes no exercise by the underwriters of their over-allotment option and excludes:

- 753,100 shares of common stock subject to future vesting issued to members of management and directors;
- 1,498,128 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan; and
- 80,000 shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters as part of this offering at an exercise price of $10.00 (assuming an initial public offering price of $8.00 per share (the midpoint of the price range set forth on the cover page of this prospectus)).

The following table summarizes, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $8.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	10,593,555	91.4%	$ 2,163,966	21.3%	$ 0.20
New investors	1,000,000	8.6%	8,000,000	78.7%	$ 8.00
Total	11,593,555	100.0%	$ 10,163,966	100%	

A $1.00 increase (decrease) in the assumed initial public offering price of $8.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $1 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 12.5 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 12.5 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 500,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $4 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 50 percentage points and, in the case of a decrease of 500,000 shares, would decrease the percentage of total consideration paid by new investors by 50 percentage points, assuming no change in the assumed initial public offering price.

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of common shares held by new investors purchasing common stock in this offering would be increased to 9.8% of the total number of shares of common stock outstanding after this offering, and the number of shares held by existing stockholders would be reduced to 90.2% of the total number of shares of common stock outstanding after this offering.

To the extent that stock options or warrants are exercised, we issue new stock options under our equity incentive plan, or we issue additional common stock in the future, there will be further dilution to investors participating in this offering. In addition, if we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

The following table sets forth our selected financial data as of the dates and for the periods indicated. We have derived the statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the three months ended March 31, 2020 and 2019 and the balance sheet data as of March 31, 2020 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

Statement of Operations Data:

(in thousands, except share and per share data)

	Years Ended December 31,		Three Months Ended March 31, (unaudited)	
	2019	2018	2020	2019
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	2,606	1,270	150	126
General and administrative	819	420	95	22
Total operating expenses	3,425	1,690	245	148
Net loss	$ (3,425)	$ (1,690)	$ (245)	$ (148)
Net loss per common share – basic and diluted[(1)]	$ (1.52)	$ (8.32)	$ (0.03)	$ (0.73)
Weighted average common shares outstanding – basic and diluted[(1)]	2,257,979	202,996	8,496,834	202,996

(1) See Note 3 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

Balance Sheet Data:

(in thousands)

	December 31,		March 31, 2020 (unaudited)
	2019	2018	
Cash	$ 7	$ 85	$ 7
Working capital deficit	(1,370)	(643)	(1,440)
Total assets	27	109	26
Total liabilities	1,377	10,229	1,447
Accumulated deficit	(27,214)	(23,789)	(27,459)
Total stockholders' deficit	(1,350)	(10,120)	(1,421)
Total liabilities and stockholders' deficit	27	109	26

You should read the following discussion and analysis of our financial condition and plan of operations together with "Selected Financial Data" and our financial statements and the related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are a biopharmaceutical company that is developing GP2, an immunotherapy designed to prevent the recurrence of breast cancer following 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. In a Phase IIb clinical trial 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. We are planning to commence a Phase III clinical trial in 2020.

To date, we have not generated any revenue and we have incurred net losses. Our net losses were approximately $3.4 million and $1.7 million for the years ended December 31, 2019 and 2018, respectively, and approximately $0.2 million and $0.1 million for the three months ended March 31, 2020 and 2019, 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.

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Results of Operations For the Years Ended December 31, 2019 and 2018

Research and Development Expenses

Research and development expenses increased by $1,336,404, or 105%, to $2,606,420 for the year ended December 31, 2019 from $1,270,016 for the year ended December 31, 2018. The increase was primarily the result of an increase in compensation expenses, license expenses, and the GMP manufacturing of GP2.

General and Administrative Expenses

General and administrative expenses increased by $399,248, or 95% to $818,887 for the year ended December 31, 2019 from $419,639 for the year ended December 31, 2018. The increase was primarily the result of an increase in compensation expenses and advisory and audit expenses.

Results of Operations For the Three Months Ended March 31, 2020 and 2019

Research and Development Expenses

Research and development expenses increased by $23,533, or 19%, to $149,891 for the three months ended March 31, 2020 from $126,358 for the three months ended March 31, 2019. The increase was primarily the result of an increase in stock compensation.

General and Administrative Expenses

General and administrative expenses increased by $72,377, or 323%, to $94,750 for the three months ended March 31, 2020 from $22,373 for the three months ended March31, 2019. The increase was primarily the result of an increase in stock compensation and costs for raising capital.

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. As of March 31, 2020 and December 31, 2019, our principal source of liquidity was our cash, which totaled $6,835, 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 Years Ended December31, 2019 and 2018

We incurred net losses of $3,425,307 and $1,689,655 during the years ended December 31, 2019 and 2018, respectively, and the increase was primarily due to an increase in compensation expense, advisory and audit expenses, license expenses, and the GMP manufacturing of GP2. Cash was $85,102 at December 31, 2018 and $6,835 at December 31, 2019 and decreased due to the following reasons:

Operating Activities

Net cash used in operating activities was $293,267 for the year ended December31, 2019 and $114,952 for the year ended December 31, 2018. The increase was primarily due to an increase in advisory and audit expenses and the GMP manufacturing of GP2.

Investing Activities

We did not use or generate cash from investing activities during the year ended December 31, 2019 and December 31, 2018.

Financing Activities

Net cash provided by financing activities was $215,000 during the year ended December31, 2019, attributable to related party loans. Net cash provided by financing activities was $200,000 during the year ended December 31, 2018, attributable to the issuance of preferred stock and related party loans as part of a transfer process between brokerage firms.

Cash Flow Activities for the Three Months Ended March 31, 2020 and 2019

We incurred net losses of $244,641 and $148,731 during the three month periods ended March 31, 2020 and 2019, respectively. The increase was primarily the result of an increase in stock compensation and costs for raising capital.

Operating Activities

Net cash used in operating activities was $0 for the three months ended March31, 2020 and $80,000 for the three months ended March 31, 2019.

Investing Activities

We did not use or generate cash from investing activities during the three months ended March 31, 2020 and March 31, 2019.

Financing Activities

We did not use or generate cash from financing activities during the three months ended March 31, 2020 and March 31, 2019.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Critical Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Cash

Cash consists primarily of deposits with commercial banks and financial institutions.

Impairment of Long-Lived Assets

We review long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups.

Stock-Based Compensation

Compensation expense related to warrants and stock granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

Research and Development Costs

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, and supplies.

Income Taxes

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of tax liabilities involves dealing with uncertainties in the application of complex tax regulations.

Basic and Diluted Loss per Share

We compute loss per share in accordance with Accounting Standards Codification ("ASC") 260 — Earnings per Share ("ASC 260"). ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the statements of operations. Basic EPS is computed by dividing net loss available to common shareholders (numerator) by the weighted average number of 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 and convertible notes payable using the if-converted method. Diluted EPS excludes all dilutive potential shares if their effect is antidilutive. During periods of net loss, all common stock equivalents are excluded from the diluted EPS calculation because they are antidilutive.

Recent Accounting Pronouncements

We have evaluated the following recent accounting pronouncements through the date the financial statements were issued and filed with the SEC and believe that none of them will have a material effect on our financial statements:

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases: Topic 842" ("ASU 2016-02"), to supersede nearly all existing lease guidance under GAAP. The guidance would require lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets. ASU 2016-02 is effective for the Company in the first quarter of its fiscal year ending December 31, 2019 using a modified retrospective approach with the option to elect certain practical expedients. The Company has no leases, thus the adoption of ASU 2016-02 will have no material impact on the Company's financial statements.

In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts from Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. The amendments in this update affect the guidance in ASU 2014-09. The core principle of the guidance in Topic 606 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendments in ASU 2016-12 do not change the core principle of the guidance in Topic 606, but instead affect only the narrow aspects noted in Topic 606. Topic 606 became effective for the Company on December 1, 2018. The Company has no revenue, thus the adoption of ASU 2016-12 will have no material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company has elected early adoption of ASU 2017-09 to conform the accounting for share-based compensation to employees and nonemployees.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present EPS in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt — Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update

are effective for fiscal years, and interim periods within those fiscal years, beginning after December15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company evaluated ASU 2017-11 and determined that the adoption of this new accounting standard did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," which modifies the accounting for share-based payment awards issued to nonemployees to largely align it with the accounting for share-based payment awards issued to employees. ASU 2018-07 is effective for us for annual periods beginning January 1, 2019. The Company evaluated ASU 2018-07 and determined that the adoption of this new accounting standard did not have a material impact on the Company's financial statements.

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.

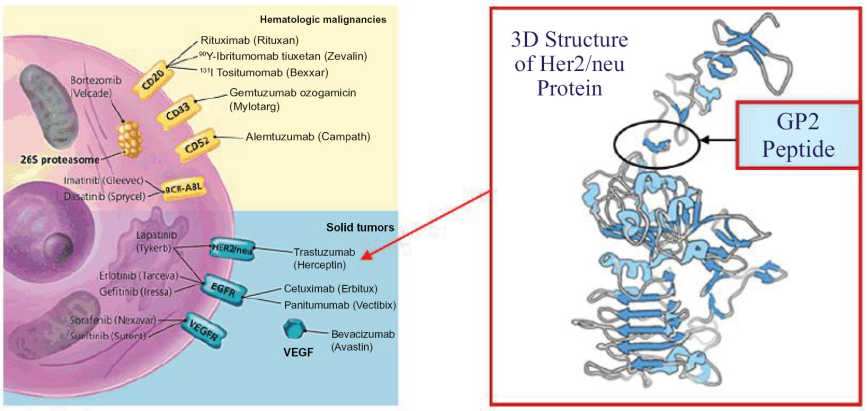
Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) 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 this 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.

Overview

We are a biopharmaceutical company that is developing GP2, an immunotherapy designed to prevent the recurrence of breast cancer following 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. In a Phase IIb clinical trial 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. We are planning to commence a Phase III clinical trial in 2020.

Our Product Candidate

GP2 is a HER2/*neu* transmembrane peptide that elicits a targeted immune response against HER2/*neu*-expressing cancers. Below is an image of a cell surface showing therapeutically relevant cell surface proteins in cancer. Breast cancers and other solid tumors with elevated expression of HER2/*neu* protein are highly aggressive with an increased disease recurrence and a worse prognosis.



GM-CSF Immunoadjuvant

Recombinant human granulocyte macrophage colony-stimulating factor or GM-CSF (sargramostim, Leukine®) has been shown to enhance monocyte as well as neutrophil cytotoxicity against melanoma tumor cells and to enhance activity-dependent cellular cytotoxicity of monocytes and neutrophils against targets coated with the anti-ganglioside antibodies. GP2 will be delivered in combination with GM-CSF to induce GP2 peptide specific immunity. GP2 treatment is administered via an intradermal injection by mixing GP2 peptide and GM-CSF at the time of administration.

GM-CSF is available in both liquid and lyophilized forms exclusively from one manufacturer, and we will continue to be dependent on such manufacturer for our supply of GM-CSF in combination with GP2 in our ongoing GP2 trials and upon potential commercialization of GP2. Although GM-CSF is currently approved for sale in the U.S. by the FDA and is available in other countries on a name patient basis through a specialized company that focuses on making products approved in the U.S. available globally, GM-CSF may be registered for sale in other countries by such manufacturer in the future.

Cancer Immunotherapy

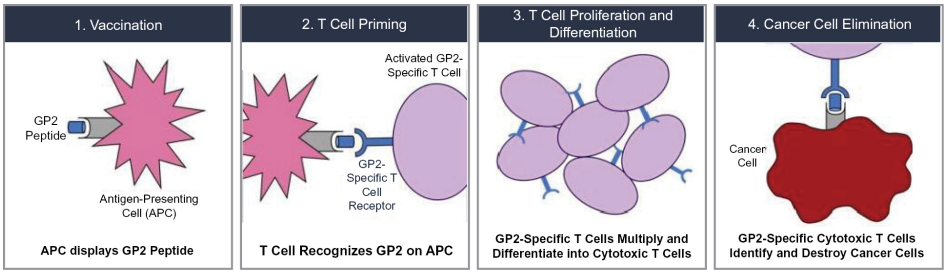
Cancer immunotherapies seek to stimulate an individual's own immune system to selectively attack cancer cells while not affecting normal cells or delivering certain immune system components in order to inhibit the spread of cancer. Cancer immunotherapy drugs are a new method of cancer treatment which are in addition to more established treatment options such as surgery, chemotherapy, targeted therapy, and radiation therapy. Therefore, cancer immunotherapy is

an important and rapidly emerging field, which has led to new clinical research studies and garnered the attention of biotechnology and pharmaceutical companies, regulatory agencies, payors and hospital systems, cancer patients and their families, and the general public at large.

Cancer immunotherapy harnesses the body's natural immune system response to fight and/or prevent tumor growth. An essential characteristic of the immune system, which is a network of tissues, cells, and signaling molecules that work to protect the body, is its ability to differentiate foreign threats, including cancerous growths, from normal cells. Despite the fact that tumor cells originate from normal cells, tumor cells can be recognized as foreign threats because of their ability to elicit the production of tumor antigens. These antigens may be released in the interstitial tissues, and eventually in the bloodstream or may remain on the surface of cognate cancer cells. The HER2/*neu* protein is one of the most widely expressed tumor antigens in multiple malignances.

Several cell types play an important role in the development and maintenance of immune responses against cancer. The most important cell types with regard to immune response are antigen-presenting cells ("APCs") and lymphocytes. APCs include various subtypes, such as dendritic cells, monocytes and macrophages. Once a patient is exposed to a tumor antigen (either by the presence of cancer itself or through active immunization through a vaccine type immunotherapeutic), the tumor antigen gets recognized by the APC and becomes "processed" through digestion into smaller fragments within the APC. Subsequently, the APC "communicates" with a specific type of lymphocyte called a T-cell. Inactive T-cells search for tumor antigens by transiently binding to antigens presented by major histocompatibility complexes ("MHCs") on the APCs. There is great variability in the expression of different subtypes of MHCs in the human population. The MHC system expresses human leukocyte antigens ("HLAs") and these HLA subtypes determine the vigor and duration of any given T-cell response to a cancer among different patients.

As shown below, following GP2 immunotherapy, CD8+ cytotoxic T lymphocytes recognize and destroy HER2/*neu*-expressing cancer cells. GP2 is administered in combination with an FDA-approved immunoadjuvant GM-CSF, which stimulates the proliferation of antigen presenting cells. Preclinical studies have shown that T cells sensitized against the GP2 peptide demonstrate significant recognition of HER2/*neu*-expressing tumors. Both ovarian and breast cancer-specific CTLs recognize GP2, which is widely expressed in HER2/*neu*-expressing tumors and is capable of inducing tumor-specific CTL populations in vitro.

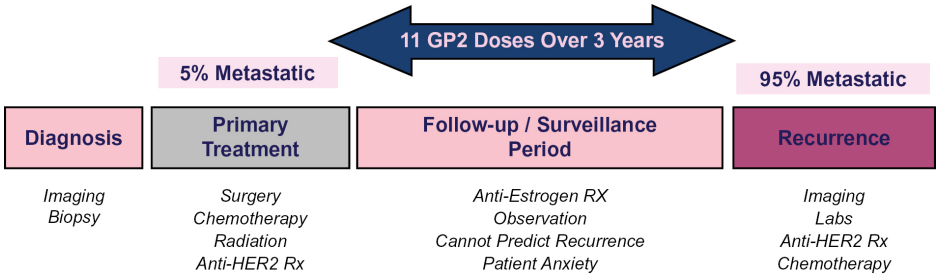


Breast Cancer Treatment Approach — Adjuvant & Neoadjuvant Treatments

As shown below, following breast cancer surgery, a HER2/*neu* 3+ patient receives Herceptin in the first year, with the hope that their breast cancer will not recur, with the odds of recurrence slowly decreasing over the first 5 years after surgery. Herceptin has been shown to reduce recurrence rates from 25% to 12% in the adjuvant setting while Kadcyla has been shown to reduce recurrence rates from 22% to 11% in the neoadjuvant setting. In the neoadjuvant setting, a patient receives treatment before surgery and, based on the results of a biopsy at surgery, will receive the same or more potent treatment after surgery. Accordingly, we believe that GP2 may be used to address the 50% of recurring patients who do not respond to either Herceptin or Kadcyla.

GP2 is administered in combination with the immunoadjuvant GM-CSF in years 2-4, following the first year of treatment with Herceptin, in a series of 11 intradermal injections comprising 6 primary injections over 6 months (1 injection per month) followed by 5 booster injections every 6 months thereafter. Furthermore, we believe that recently approved drugs such as Perjeta and Nerlynx do not fully address this unmet need, even in their most efficacious subpopulations, and that in the initial GP2 indication, approximately 17,000 new patients may be eligible for GP2 treatment per year, which could save approximately 1,500 to 2,000 lives per year.

As only injection site reactions were observed (which speaks to the immunogenicity of GP2) and no SAEs were reported in the GP2 Phase IIb clinical trial, GP2 may be positioned as the final treatment for patients post-surgery. Furthermore, we believe that clinicians and patients are seeking a de-escalation and a return to normal life free of toxic treatments, especially if the chance of recurrence is reduced substantially. Lastly, we believe that GP2 may be the treatment that will synergistically overlap with or follow Herceptin, Kadcyla, or Enhertu (fam-trastuzumab deruxtecan-nxki, DS-8201) or any of the other Herceptin derivatives or antibody drug conjugates being developed.



We believe that U.S. academic centers will be moving higher risk, node positive patients into neoadjuvant treatment and will use Kadcyla if residual disease is observed at the time of surgery; however community centers and international markets may not move as quickly or at all, due to the high dual therapy costs and the lack of approval or reimbursement of Kadcyla in markets outside of the U.S. and Europe. GP2 will be pursued in both the adjuvant and neoadjuvant settings in HER2/*neu* 3+ patients in our planned Phase III trial.

GP2 Clinical Data & Planned Phase III Trial

In the Phase IIb and three Phase I clinical trials where 138 patients received GP2 immunotherapy, there were no SAEs reported in any of the trials, including for GP2 and GM-CSF combination treatments or any other GP2 combination treatments.

Clinical Trial Description	Status
GP2 Phase IIb Clinical Trial • Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/*neu* Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-A02+ 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
GP2 Phase I Clinical Trial — Combination with AE37 • 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
GP2 Phase I Clinical Trial — Combination with Trastuzumab • Phase Ib Trial of Combination Immunotherapy with HER2/*neu* Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients • 17 patients treated with GP2 + GM-CSF + trastuzumab	Trial Completed
First GP2 Phase I Clinical Trial • Phase Ib Trial of HER2/*neu* Peptide (GP2) Vaccine in Breast Cancer Patients • 18 patients treated with GP2 + GM-CSF	Trial Completed

Phase I Clinical Trials

First GP2 Phase I Clinical Trial

As shown in the table above, the first GP2 Phase I clinical trial was conducted at Walter Reed Army Medical Center. The study was conducted in patients over the age of 18 years with a diagnosis of HER2/*neu* 1-3+, node negative breast cancer who had undergone primary surgical and medical therapies and who were without evidence of disease at the time of enrollment into the study. Patients were HLA typed and HLA-A02 patients were skin tested for recall antigens. HLA-A02 patients found to be immunologically intact received the vaccine. There were no grade 3-5 toxicities among the 18 patients receiving a total of 108 doses of GP2 + GM-CSF. Among all patients, the maximum local toxicity occurring during the entire series was grade 1 in 38.9% and grade 2 in 61.1% of the patients. The maximum systemic toxicity during the series was grade 0 in 5.6%, grade 1 in 61.1%, and grade 2 in 33.3% of the patients. The most common local reactions included erythema and induration (100% of patients), pruritis (25%), and inflammation (23%). The most common systemic reactions were grade 1 fatigue (40%) and grade 1 arthralgia/myalgia (15%). There were no recurrences and no deaths reported in study subjects. Additional data analysis included topics such as pre-existing immunity, dosing, and epitope spreading.

GP2 Phase I Clinical Trial — Combination with Trastuzumab

Preclinical research has previously demonstrated that a synergy may exist between trastuzumab and GP2 peptide-stimulated CTLs ex vivo. Pretreatment of breast cancer cells with trastuzumab followed by incubation with GP2 peptide-induced CTLs resulted in enhanced cytotoxicity in 3 tumor cell lines compared to treatment with trastuzumab or GP2-specific CTLs alone. These results suggest that concurrent GP2 vaccination during trastuzumab therapy may be a possible combination immunotherapy.

As shown in the table above, a Phase I trial evaluating the combination therapy of GP2 + GM-CSF administered simultaneously with trastuzumab was conducted. The combination therapy was found to be well tolerated when given concurrently in 17 clinically disease-free, HER2/*neu* over-expressing breast cancer patients.

GP2 Phase I Clinical Trial — Combination with AE37

As shown in the table above, a Phase I trial evaluating the combination therapy of GP2 + GM-CSF administered simultaneously with HER2/*neu* peptide AE37 in 14 clinically disease-free, HER2/*neu* breast cancer and ovarian cancer patients was conducted. While 28 patients enrolled, 14 patients completed the 6 vaccination series. Initial results suggest that combining GP2 and AE37 peptides is well tolerated at all tested dosing levels. Additionally, we believe the combination is capable of stimulating strong peptide-specific in vivo immune responses.

During the primary vaccination series, an AE37/GP2+GM-CSF dual peptide vaccine resulted in robust T-cell proliferation. However, significant immune responses became more variable at 6 and 12 months post vaccination suggesting the need for boosters in some individuals.

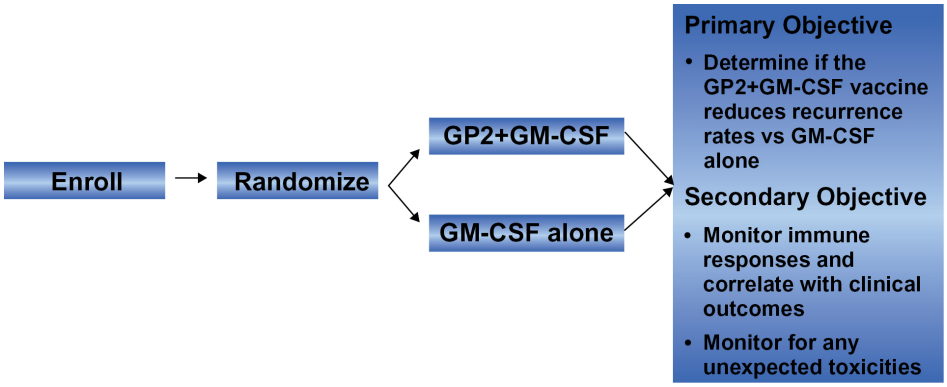
Phase II Clinical Trial

GP2 Phase IIb Clinical Trial

In a randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial of HLA-A02 breast cancer patients, the combination of GP2-GMCSF-Herceptin treatment resulted in no recurrences in 46 HER2/*neu* 3+ over-expressor patients who were fully treated with GP2 versus 50 placebo patients who were treated with GMCSF-Herceptin and who recurred at a rate similar to historical recurrence rates for patients treated with Herceptin. After median 5 years of follow-up, there were 0% cancer recurrences in the HER2/*neu* 3+ patients treated with GP2-GMCSF-Herceptin, if the patient received the 6 primary intradermal injections over the first 6 months, versus an 11% cancer recurrence rate in the placebo arm treated with GMCSF-Herceptin ($p = 0.0338$). Thus, sequentially combining Herceptin in year 1 and GP2-GMCSF in years 2-4 may dramatically lower breast cancer recurrences in this patient population.

The design of the Phase IIb trial was as follows:

- Prospective, randomized, single-blinded, placebo-controlled phase IIb clinical trial of GP2 + GM-CSF or GM-CSF alone in HER2/*neu* 1-3+, HLA-A02 patients.
- High-risk breast cancer patients (Node Positive, High Risk Node Negative) who were disease-free and immunocompetent after having completed standard of care therapy.
- The primary endpoint was to determine if GP2 + GM-CSF reduces breast cancer recurrence rates versus GM-CSF alone. A recurrence is defined as either a pathologically confirmed recurrence or a new radiographic finding during standard of care follow-up.



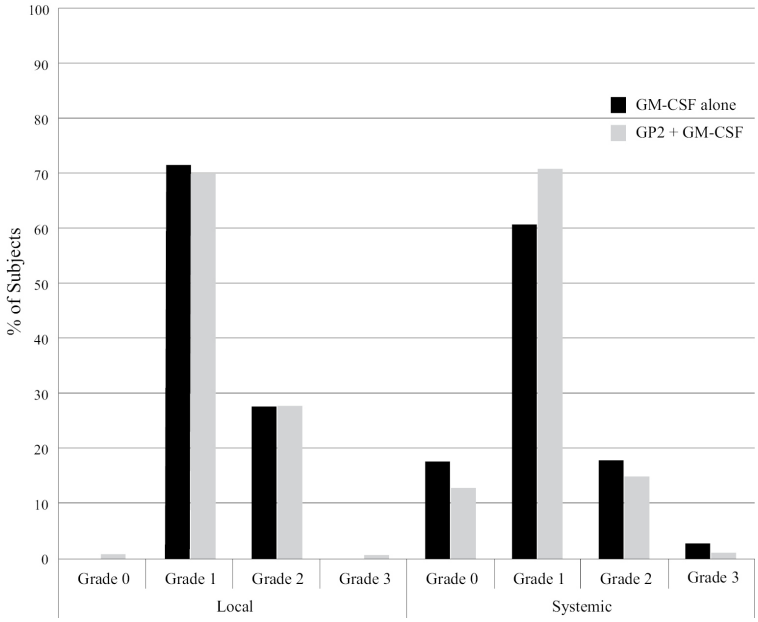
The Phase IIb clinical trial closed in December 2018. The median 5 year follow-up data from this Phase IIb clinical trial is currently being collected and analyzed. The median 5 year data, other than the top-line data described in the table below, has yet to be published.

GP2 + GM-CSF Treated Patients Recurrence Rate	GM-CSF Placebo Patients Recurrence Rate	Hazard Ratio	Kaplan-Meier Survival Analysis
0.0%	11.0%	0.00	*p = 0.0338*

A median 3 year interim analysis of the GP2 Phase II trial was published in 2016 and presented efficacy, safety, and immunological data, and a median 4 year interim analysis of the GP2 Phase II trial was published in April 2020. Of the total 180 intent-to-treat patients enrolled, 168 patients completed the 6 primary intradermal injection series over the first 6 months. HER2/*neu* status was determined based on the expression levels of the HER2/*neu* protein in each patient using standard of care HER2/*neu* diagnostic technology. The trial was prospectively designed to analyze these fully treated patients by 2 distinct patient populations, namely HER2/*neu* 3+ (over expressors) and HER2/*neu* 1-2+ (low to intermediate expressors):

- HER2/*neu* 3+ Over Expressors: In the 96 HER2/*neu* 3+, HLA-A02 patients, no recurrences were observed if the patient received the 6 primary intradermal injections over the first 6 months following the first year of Herceptin treatment. This is the target population for our planned Phase III trial.
- HER2/*neu* 1-2+ Low to Intermediate Expressors: In the 72 HER2/*neu* 1-2+, HLA-A02 patients, no reduction in recurrence rates were observed, but Herceptin was not administered to these patients. Thus, we may pursue a future trial with GP2 in combination with Herceptin therapy.

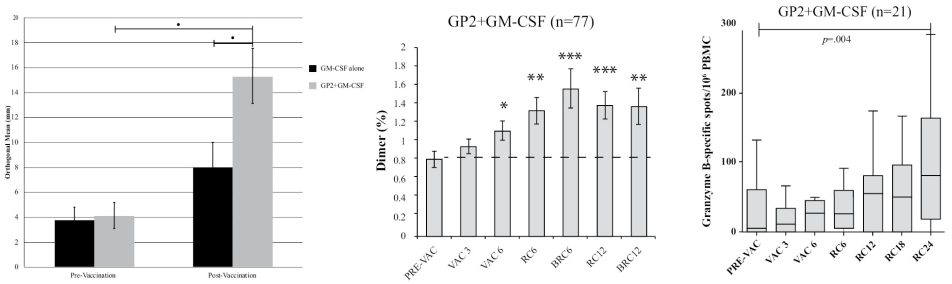
In both patient populations, GP2 was shown to be well tolerated, consisting of primarily injection site reactions which are caused by GM-CSF and can be mitigated by reducing the GM-CSF dose (and then the GP2 dose, if necessary). No SAEs were reported in the GP2 treated patients. Maximum local and systemic 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, and not to 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 primary vaccination series 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.

GP2 immunotherapy elicited a potent immune response in HLA-A02 patients after they received the 6 primary intradermal injections over the first 6 months. The immune response was measured by a local skin test and immunological assays. Further, booster injections given every 6 months thereafter prolonged the immune response, thereby providing longer term protection.

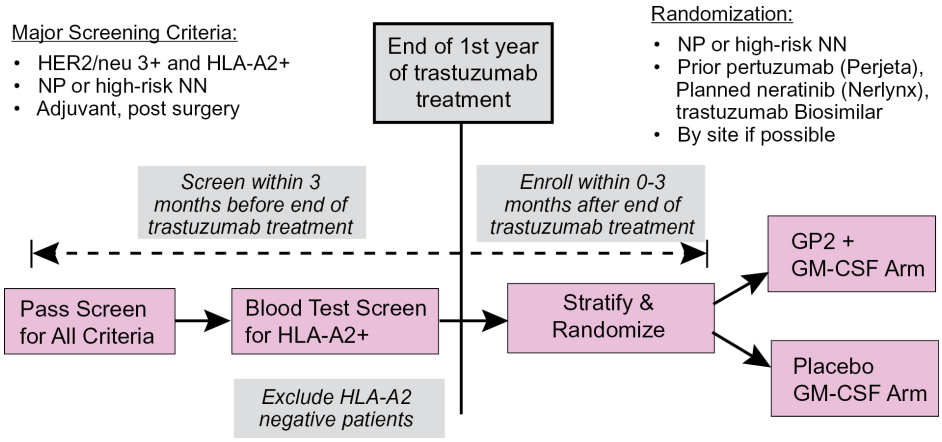
- Immune response was observed peaking after 6 months compared to baseline, measured by Delayed Type Hypersensitivity (("DTH") skin test using GP2) and immunological assay. DTH response rate for treated patients is very high. Orthogonal mean baseline versus six months: 4.1±1.1mm versus 15.3± 2.2mm (± standard error).
- Boosters were administered every 6 months to sustain immunity.



Planned Phase III Trial

We are planning to launch a Phase III clinical trial in 2020, using a similar treatment regime as the Phase IIb clinical trial. The manufacturing plan and the Phase III trial protocol have been reviewed by the FDA, and final revisions to the Phase III trial protocol are under way, which may include an interim analysis/adaptive trial design that will result in the finalization of the size of the trial. The primary endpoint of the Phase III clinical trial will compare recurrence rate of GP2 + GM-CSF treated patients versus placebo patients at various time points using standard of care follow-up. We believe that it may require up to 2 years to fully enroll all patients for the trial, and that we may follow-up patients for up to a median 5 years following enrollment in such trial; however the addition of an interim analysis may reduce the time required to report clinical data and to file a BLA application. These design features of the Phase III clinical trial are currently being finalized by the Company's clinical advisors.

An overview of the Phase III clinical trial design is shown below.



We have commenced GP2 manufacturing, and we are currently in the process of finalizing our engagement of CMOs and CROs for the Phase III clinical trial.

Large Initial & Expandable Breast Cancer Market

We believe that the potential market for the proposed initial and follow-on indications is large. HER2/*neu* 3+ breast cancer patients comprise approximately 25% of all breast cancer patients. Approximately 40% to 50% of the U.S. population contains the HLA-A02 allele, while node positive and high risk node negative patients comprise approximately 50% of the market. Therefore, we believe that the initial market for GP2 could be the combination of the three populations above which together comprises 6% of breast cancer patients. We believe that follow-on indications could include additional HLA types (an additional 30% of the U.S. population) and the low to intermediate

expressors of HER2/*neu* 1-2+ patients (an additional 50% of all breast cancer patients) which would expand the GP2 market from our estimated initial 6% to 30% of breast cancer patients who undergo surgery. Thus the market for GP2, including follow-on indications, could be 2.4 times the current Herceptin adjuvant setting market, which constitutes approximately 12.5% of breast cancer patients.

We believe that the potential market for GP2 could be estimated as follows, with the long term multi-billion dollar annual revenue potential of GP2 based on 16,750 to 79,800 potential new patients treated per year and Herceptin's 2018 annual per patient price of $74,500:

- **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)	$2-3	
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)	$7	
Adjuvant Setting	$2-3	Multi $ Billion Revenue Potential
Metastatic Breast Cancer	$4-5	

Competition

Cancer immunotherapy has become a significant growth area for the biopharmaceutical industry, attracting large pharmaceutical companies as well as small niche players. Generally, our principal competitors in the cancer immunotherapy market comprise both types of companies with currently approved products for various indications, such as manufacturers of approved bispecific antibodies, CAR-T cells, and checkpoint inhibitors, as well as companies currently engaged in cancer immunotherapy clinical development. The large and medium-size players who have successfully obtained approval for cancer immunotherapy products include Bristol-Myers Squib Company, Merck & Co., Inc., Genentech, Inc. (a subsidiary of Roche Holding AG), AstraZeneca PLC, Celgene Corporation, Johnson & Johnson, Amgen, Novartis, Juno Therapeutics, Inc. (a subsidiary of Celgene), Kite Pharma, Inc., a wholly-owned subsidiary of Gilead Sciences, Inc. and Pfizer, Inc./EMD Serono, Inc. Most of these companies, either alone or together with their collaborative partners, have substantially greater financial resources than we do.

Companies developing novel products with similar indications to those we are pursuing are expected to influence our ability to penetrate and maintain market share. For patients with early stage breast cancer, adjuvant therapy is often given to prevent recurrence and increase the chance of long-term disease free survival. Adjuvant therapy for breast cancer can include chemotherapy, hormonal therapy, radiation therapy, or combinations thereof. In addition, the HER2 targeted drug Herceptin (trastuzumab) alone or in combination with Perjeta (pertuzumab), both manufactured and marketed by Roche/Genentech, may be given to patients with tumors with high expression of HER2/*neu*.

There are a number of approved HER2/*neu* targeted therapies, some of which include the following: Genentech's Herceptin, Perjeta and Kadcyla (TDM-1, ado-trastuzumab emtansine); Puma's Nerlynx; Daichi Sanko's Enhertu (DS-8201, fam-trastuzumab deruxtecan-nxki), and Seattle Genetics' (Tukysa, tucatanib). In addition, the following biosimilars to trastuzumab have been approved: Biocon/Mylan's (Ogivri — trastuzumab-dkst; Celltrion/Teva's (Herzuma — trastuzumab-pkrb); Samsung/Biogen/Merck's (Ontruzant — trastuzumab-dttb); Pfizer's (Trazimera — trastuzumab-qyyp); and Allergan/Amgen's (Kanjinti; trastuzumab-anns). Furthermore, the following immune checkpoint inhibitors have also been approved or are under review by the FDA to treat breast cancer patients: Merck's Keytruda (pembrolizumab) and Genentech's Tecentriq (atezolumab). Moreover we believe that drug candidates from Sellas (formerly Galena), Marker (formerly TapImmune), Epithany, Antigen Express (Generex subsidiary), and various companies pursuing neoantigen technologies are in clinical development and are being pursued for different sub-populations or are behind GP2 in clinic development.

We believe that GP2 will act synergistically with Herceptin, Perjeta, Nerlynx, and the newest entrants Kadcyla and Enhertu.

- 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.

Approved on Y3 Post-Surgery Data

- 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%).

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

Herceptin ADC 4:1

Herceptin ADC 8:1

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and more experience in obtaining FDA and other regulatory approvals of treatments and in commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for cancer immunotherapy products and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize, thus causing limited market share before we can recover the expenses of developing and commercializing our cancer immunotherapy product candidate.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These activities may lead to consolidated efforts that allow for more rapid development of cancer immunotherapy product candidates.

These competitors also compete with us in the recruiting and retaining of qualified scientific and management personnel, the ability to work with specific clinical contract organizations due to conflict of interest, and the conduct of trials in the ability to recruit clinical trial sites and subjects for our clinical trials.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price, and the availability of coverage and reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more convenient, or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our current product candidate or any other future product candidate, which could result in our competitors establishing a strong market position before we are able to enter the market.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidate nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients ("APIs"), and finished product candidate for our clinical trials. We do not have any current contractual arrangements for the manufacture of commercial supplies of our product candidate.

For prior clinical trials, GP2 was formulated, filled, labeled, stored, tested, packaged, and distributed to clinical sites by the pharmacy at the Walter Reed Medical Center and the HJF. For future clinical trials, we anticipate that GP2 will be formulated, filled, labeled, stored, tested, packaged, and distributed to clinical sites in licensed cGMP manufacturing facilities as we evaluate and select primary and secondary facilities which may also serve as commercial facilities.

Exclusive License

The Henry M. Jackson Foundation out-licenses technology of the United States military and it conducts research and manages clinical trials. HJF managed the GP2 Phase IIb clinical which was led by MD Anderson Cancer Center, oversaw all regulatory filings with the FDA for all 4 GP2 clinical trials (including the three Phase I and the Phase IIb clinical trials), and possesses all patient and manufacturing data from such trials.

In April 2009, we entered into an exclusive license agreement, as amended, with HJF pursuant to which HJF granted us exclusive worldwide rights to several U.S. and foreign patents and patent applications covering methods of using GP2 as an immunotherapy that elicits a targeted immune response against HER2/*neu*-expressing cancers. In consideration for such licensed rights, we issued HJF 202,619 shares of our common stock. In addition, we are required to pay an annual maintenance fee and milestone payments of up to an aggregate of $5.7 million. We are also required to make 2.5-5% royalty payments based on the sales of GP2 and to reimburse HJF for patent expenses. To date we have not been required to make any milestone or royalty payments to HJF. The term of the exclusive license shall terminate at such time that the last licensed patent or patent application expires or is abandoned, unless terminated earlier pursuant to the terms of the exclusive license agreement. We may terminate the license by giving 90 days notice. HJF may terminate the license if we do not make required payments, if we default in our performance obligations, if we do not sufficiently develop and advance GP2 towards commercialization, and for various other reasons.

In connection with the exclusive license agreement with HJF, we were the financial and corporate sponsors of the GP2 Phase IIb clinical trial. HJF has provided us with all FDA correspondences and GP2 patient and manufacturing data for the history of the drug's development for all 4 clinical trials, and we have incorporated this data into our corporate investigational new drug application ("IND") with the FDA.

Intellectual Property Portfolio

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable, and our ability to prevent others from infringing our proprietary rights. We intend to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring European Union oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework, and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. Patents and other intellectual property rights are crucial to our success. We intend to protect our intellectual property rights through available means including filing and prosecuting patent applications in the U.S. and other countries, protecting trade secrets, and utilizing regulatory protections such as data exclusivity. In addition, we include restrictions regarding use and disclosure of our proprietary information in our contracts with third parties, and utilize customary confidentiality agreements with our employees, consultants, clinical investigators, and scientific advisors to protect our confidential information and know-how. Together with our licensors, we also rely on trade secrets to protect our combined technology especially where we do not believe patent protection is appropriate or obtainable. It is our policy to operate without knowingly infringing on, or misappropriating, the proprietary rights of others.

An international patent law treaty ("PCT") provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. Thus, a single PCT application can be converted into a national stage patent application in any of the more than 145 PCT contracting states, and is considered a simple, cost-effective means for seeking patent protection in numerous regions or countries. This nationalization (converting into an application in any of the contracting states) typically occurs 18 months after the PCT application filing date. We also rely on trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the U.S., the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the U.S., a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

HJF License

Pursuant to our exclusive license agreement with HJF, we were granted exclusive worldwide rights to several U.S. and foreign patents and patent applications covering methods of using GP2. The GP2 issued patents provide protection ranging from 2026 through 2032 in major markets such as the U.S., Europe, Japan, Australia, and Canada, with ongoing prosecution of pending patent applications in other markets. We plan to register GP2 as a biologic, which may be subject to 10-12 years market exclusivity in the U.S. upon receiving marketing approval.

The following summarizes the two patent families subject to our exclusive license agreement with HJF. We have licensed rights to issued patents and pending patent applications in certain countries with respect to the two patent families below and do not own or have rights to any other patents or patent applications for GP2 or any other products:

- GP2 + GM-CSF Patent Family — A patent application has been filed and licensed describing methods and compositions for the induction of a cytotoxic T-cell response to the GP2 peptide with the effect of inducing and maintaining a protective or therapeutic immunity against breast cancer. Patent claims describe the use of the GP2 technology including dosing, formulation, identification of patients, and use in combination with GM-CSF. Patents issued in the U.S. will expire in 2032 and 2029 and international patents will expire in 2029.

- GP2 + Herceptin Patent Family — A patent application has been filed and licensed describing methods and compositions of GP2 peptide in combination with a HER2/*neu* targeting antibody such as Herceptin. U.S. and certain foreign patent claims describe the method and timing of administration. Patents issued in the U.S. will expire in 2028 and 2026 and international patents will expire in 2026.

Corporate Strategy

We do not have a sales, marketing, or product distribution strategy for our GP2 immunotherapy or any future product candidates because GP2 is still in clinical development. Our future commercial strategy may include the use of strategic partners, distributors, a contract sales force, or the establishment of our own commercial and specialty sales force for the U.S. market, as well as similar strategies for regions and territories outside the U.S. We plan to further evaluate these options as we approach approval for the use of our product candidate for one or more indications.

The GP2 issued patents provide protection ranging from 2026 through 2032 in various markets, and we plan to register GP2 as a biologic, which may be subject to 10-12 years market exclusivity in the U.S. upon receiving marketing approval. During this period of exclusivity, we intend to advance GP2 into a Phase III clinical trial in the U.S. and pursue a European and global clinical trial strategy to support GP2 registration outside of the U.S. We are considering various options to fund the Phase III clinical trial including financing and/or strategic transactions. Our strategy during such time also includes building a commercialization team, pursuing additional funding after this offering, and pursuing strategic collaborations to support the future global marketing and sales of GP2. A long term global and regional licensing process has been initiated and will continue as the Phase III trial commences.

Pipeline Strategy — Including GP2 In Other HER2/*neu*-Expressing Cancers

We are developing follow-on indications for GP2 by designing and planning additional clinical trials to expand the breast cancer patient population and to pursue additional HER2/*neu*-expressing cancers. Pending the receipt of sufficient capital, the planned Phase III clinical trial can be supplemented with the following pipeline investments:

- The efficacy of GP2-GMCSF-Herceptin can be explored in (1) other HLA patients in the same HER2/*neu* 3+ breast cancer patient population, (2) breast cancer patients who are low to intermediate expressors of HER2/*neu* (1-2+) and who comprise two-thirds of the triple negative market, or (3) other HER2/*neu*-expressing cancers including, but not limited to, ovarian, gastrointestinal, and colon cancers.
- We may acquire a preclinical platform that can be quickly advanced into IND-enabling GMP manufacturing and GLP toxicology studies followed by initial human clinical trials.

Government Regulations

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. Along with third-party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our current product candidate or any future product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label.

The process required by the FDA before biologic product candidates may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;

- approval by an independent IRB or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S., which must be updated annually when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our current product candidate or any future product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by a Data and Safety Monitoring Board, or DSMB, organized by the clinical trial sponsor, which provides authorization for whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- **Phase 1** — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- **Phase 2** — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- **Phase 3** — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.
- **Phase 4** — In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific

prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a product candidate with Fast Track designation, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A Fast Track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Accelerated Approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, a sponsor may seek FDA designation of its product candidate as a Breakthrough Therapy, if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis.

Fast Track, Priority Review and Breakthrough Therapy designations do not change the standards for approval but may expedite the development or approval process.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the U.S. in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Our promotional and

scientific/educational programs must comply with the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, the False Claims Act, or FCA, the Veterans Health Care Act, physician payment transparency laws, privacy laws, security laws, and additional state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors.

The FCA imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multibillion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which it conducts its business. HIPAA, as amended by HITECH, and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to it, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidate, if approved, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our product candidate. Seeking coverage and reimbursement from third-party payors can be time consuming and expensive. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our product on a competitive and profitable basis.

Foreign Regulation

In addition to regulations in the U.S., we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and commercial sales and distribution of our product, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have processes that require the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company plans to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of a new drug or medicinal product in the European Union, a sponsor must obtain approval of a marketing authorization application. The way in which a medicinal product can be approved in the European Union depends on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated as "orphan drugs" and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may, at the request of the applicant, also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure, or MRP, for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. The MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national marketing authorization by one or more member states.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a member state of the E.U. that is used as reference in order to obtain marketing authorizations in other E.U. member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the E.U. and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states.

The MRP is based on the principle of the mutual recognition by European Union member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of June 15, 2020, we had no full-time employees and 3 part-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Facilities

As of June 15, 2020, we do not operate a facility and instead contract research and development to commercial contract facilities. However, as we conduct manufacturing and clinical trial operations in the future, we may sub-lease or lease a facility to support such operations.

Legal Proceedings

We may be involved from time to time in ordinary litigation, negotiation, and settlement matters that will not have a material effect on our operations or finances. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened litigation against us.

Directors and Executive Officers

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of June 15, 2020.

Name	Age	Position
Snehal Patel	56	Chief Executive Officer, Chief Financial Officer and Director
F. Joseph Daugherty	69	Chief Medical Officer and Director
Jaye Thompson	54	Vice President Clinical & Regulatory Affairs
David McWilliams	77	Chairman of the Board
Eric Rothe	45	Director
Kenneth Hallock	71	Director

Snehal Patel. Snehal Patel has over 30 years of experience in executive management, corporate development, operations, and investment banking in the healthcare industry. Mr. Patel has served as our Chief Executive Officer since June 2016 and our Chief Financial Officer and a member of our board of directors since February 2010. In addition, since 2009, Mr. Patel has served as a consultant, manager, and advisor at various levels in multiple private start-up biotech companies helping to develop clinical and pre-clinical assets in cancer and other therapeutic areas. Prior to 2010, Mr. Patel served as a consultant to public and private companies focused on stem cell therapy, multiple sclerosis t-cell therapy, oncolytic viruses, and disposable biotech manufacturing equipment. In addition, Mr. Patel previously served as an investment banker at Sanders Morris Harris, Ferghana Partners, and JP Morgan Chase focusing on healthcare and biotech financing and strategic transactions. Mr. Patel also previously worked in operations and business development at Bayer Corporation and in design and operations consulting firms. Mr. Patel received a Bachelor of Science degree in chemical engineering and a Master of Science degree in biochemical engineering from the Massachusetts Institute of Technology and a Masters of Business Administration degree from the University of Chicago. We believe Mr. Patel is qualified to serve as a member of our board of directors because of his executive and management experience working with biotech companies.

F. Joseph Daugherty. F. Joseph Daugherty has over 35 years of experience in managing and overseeing biotechnology and biomedical projects. Dr. Daugherty has served as our Chief Medical Officer since September 2019 and a member of our board of directors since September 2019. In addition, since 2002, Dr. Daugherty has served as the Managing Partner of Phenolics, LLC and PharmaPrint, LLC which was spun off from Phenolics, LLC, both of which are nutraceutical companies. From 2002 until 2018, he served first as President, and since 2008 as Chief Executive Officer, Chief Medical Officer and the Chairman of the board of directors of Eleos Inc., a clinical stage private biotech company focused on anti-sense technology in cancer. Dr. Daugherty also served in various other capacities as a management consultant as well as an officer and director to over 20 public and private biomedical companies including Dupont. In addition, Dr. Daugherty was President of ConAgra's biotech division. Dr. Daugherty received a Bachelor of Arts degree in biology from Washington University, a Doctor of Medicine degree from the University of Nebraska Medical Center and a Masters of Science in Industrial Administration from Carnegie-Mellon University (Tepper). We believe Dr. Daugherty is qualified to serve as a member of our board of directors because of his executive and management experience, including his experience working with biotech companies.

Jaye Thompson. Jaye Thompson has over 30 years of experience in pharmaceutical and device product development. Dr. Thompson has served as our Vice President Clinical & Regulatory Affairs since September 2019. Since December 2017, Dr. Thompson has served as a co-founder and Chief Operating Officer of Proxima Clinical Research, Inc., a clinical research service provider. Dr. Thompson previously served as Senior Vice President of Clinical and Regulatory Affairs of Repros Therapeutics, a reproductive health company, from March 2013 to May 2017 and as a member of the board of directors of Repros Therapeutics from November 2009 to March 2013. Dr. Thompson previously served as Senior Vice President of Clinical Development and Regulatory Affairs of Opexa Therapeutics, a multiple sclerosis cell therapy company, from September 2009 to March 2013. In addition, Dr. Thompson has served at clinical stage biotech companies, in various senior clinical and regulatory roles and at inVentiv Clinical Solutions, a clinical research service provider. Dr. Thompson was the president and founder of SYNERGOS, Inc., a clinical research service provider, which was founded in 1991, and acquired by inVentiv Health, as a wholly-owned subsidiary in 2006. Dr. Thompson has advised several of the region's leading life science companies on strategic and regulatory planning as well as clinical product development. She has directed and managed statistical analysis, data

management, report writing, and the conduct of clinical trials for a wide variety of indications. Dr. Thompson has been actively involved in over 200 clinical trials for drugs, biologics and devices, and has been associated with numerous FDA regulatory submissions. Dr. Thompson has often represented sponsor companies at FDA meetings and advisory committee meetings, and she was appointed to the Governor's Texas Emerging Technology Fund Advisory Committee. Dr. Thompson received a BS in applied mathematics from Texas A&M University and an MS and a PhD in biostatistics from the University of Texas Health Science Center in Houston.

David McWilliams. David McWilliams has over 40 years of experience in building biopharmaceutical and healthcare companies. Mr. McWilliams has served as a member of our board of directors since February 2009. He previously served as the Chief Executive Officer from February 2010 to June 2016 and Chairman of the board of directors of the Company since February 2009. In addition, since 2008, Mr. McWilliams has served as a consultant and an advisor at various levels in multiple private start-up biotech companies to help develop clinical and pre-clinical assets in cancer and other therapeutic areas. Mr. McWilliams previously served as the Chief Executive Officer and a member of the board of directors of Opexa Therapeutics, Inc., a multiple sclerosis cell therapy company, from 2004 until 2008. Mr. McWilliams also previously served as the Chief Executive Officer, President and a member of the board of directors of Bacterial Barcodes, Inc., a bacteria and fungi diagnostic company, and the Chief Executive Officer and a member of the board of directors of Signase, Inc., a cancer therapeutics company. Mr. McWilliams has also served in various other capacities including Chief Executive Officer, President and a member of the board of directors of both Encysive Pharmaceuticals, Inc. and Repros Therapeutics Inc.; Chief Executive Officer and President of Kallestad Diagnostics (Erbamont); President of Harleco Diagnostics Division (EM Industries); General Manager and Program Manager of Abbott Laboratories; and Management Consultant at McKinsey & Company. In addition to the foregoing, Mr. McWilliams currently serves as the Chairman of the board of directors of BioHouston, an advocate of the life sciences industry in Houston. Mr. McWilliams received a Bachelor of Arts degree in chemistry from Washington and Jefferson College and a Master of Business Administration degree from the University of Chicago. We believe Mr. McWilliams is qualified to serve as a member of our board of directors because of his executive experience, management experience and experience working with biotech companies.

Eric Rothe. Eric Rothe is the founder of the Company and has over 12 years of industry and academic experience in gene-based therapies and vaccines, including six years of laboratory experience. Mr. Rothe previously served as President of the Company from October 2006 to February 2010, Chief Executive Officer of the Company from October 2007 to February 2010 and Chairman of the Company's board of directors from October 2006 to February 2009. In addition, Mr. Rothe has served as a member of the Company's board of directors since August 2006. Since August 2017, Mr. Rothe has served as the Global Product Line Leader at Baker Hughes, an energy technology company. Previously, from September 2014 until its acquisition by GE Oil & Gas' acquisition of Baker Hughes in July 2017, Mr. Rothe served as Vice President of Mid-Continent and NE US Geomarket and Global Product Line Leader of GE Oil & Gas. From 2012 to 2014, Mr. Rothe served as the International Sales and Operations Director at National Oilwell Varco, one of the world's largest oil field equipment providers. Before joining the oil & gas sector, Mr. Rothe was Director of the Clinical Cancer Genetics program at U.T. M.D. Anderson Cancer Center, Project Manager at Introgen, a developer of cancer products in advanced clinical trials, and provided consulting services for start-up/small biotechnology companies in Texas. Mr. Rothe received a Bachelor of Arts degree in molecular and cell biology from the University of California at Berkeley and a Master of Business Administration degree from Rice University. We believe Mr. Rothe is qualified to serve as a member of our board of directors because of his expertise in cancer immunology, GMP manufacturing, and clinical research, and his experience in various senior management positions in global commercial operations at large corporations.

Kenneth Hallock. Kenneth Hallock has over 40 years of experience in general management and new venture start-ups and is a major investor in our Company. Mr. Hallock has served as a member of our board of directors since September 2019. Mr. Hallock is currently a senior manager and partner in a private start-up equipment manufacturing company and has been in this role for over 10 years. Previously, Mr. Hallock worked in large industrial corporations such as NL Industries and Anderson Clayton, which were subsequently acquired. Mr. Hallock received a Bachelor of Engineering degree in chemical engineering from Princeton University and a Master of Business Administration degree from Harvard Business School. We believe Mr. Hallock is qualified to serve as a member of our board of directors because of his experience in various management positions for several Fortune 500 companies.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Director Independence

Prior to the consummation of this offering, our board of directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that David McWilliams, Eric Rothe and Kenneth Hallock are each an "independent director," as defined under the Nasdaq rules.

Committees of Our Board of Directors

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and its standing committees. We will have a standing audit committee and compensation committee. Our entire board of directors will serve in place of a nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Audit Committee

Our audit committee will be responsible for, among other things:

- Approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Upon the consummation of this offering, our audit committee will consist of David McWilliams, Eric Rothe and Kenneth Hallock, with David McWilliams serving as chair. Our board of directors has affirmatively determined that David McWilliams, Eric Rothe and Kenneth Hallock each meet the definition of "independent director" under the Nasdaq rules, and that they meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that David McWilliams will qualify as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors will adopt a written charter for the audit committee, which will be available on our principal corporate website at *www.greenwichlifesciences.com* concurrently with the consummation of this offering.

Compensation Committee

Our compensation committee will be responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Upon the consummation of this offering, our compensation committee will consist of David McWilliams, Eric Rothe and Kenneth Hallock, with David McWilliams serving as chair. Our board has determined that David McWilliams, Eric Rothe and Kenneth Hallock are independent directors under Nasdaq rules. Our board of directors will adopt a written charter for the compensation committee, which will be available on our principal corporate website at *www.greenwichlifesciences.com* concurrently with the consummation of this offering.

Nominating and Governance

Although our entire board of directors will serve in place of a nominating and corporate governance committee, our independent directors on the board will be responsible for, among other things:

- nominating members of the board of directors;
- developing a set of corporate governance principles applicable to our company; and
- overseeing the evaluation of our board of directors.

Upon the consummation of this offering, our entire board of directors will serve in place of a nominating and corporate governance committee. Our board of directors will adopt resolutions addressing, among other things, the nomination process.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code will be posted on our website, *www.greenwichlifesciences.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our Second Amended and Restated Certificate of Incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Second Amended and Restated Certificate of Incorporation to be in effect upon the closing of this offering will provide that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Second Amended and Restated Bylaws to be in effect upon the closing of this offering will provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our Second Amended and Restated Bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our Second Amended and Restated Bylaws will also provide our board of directors with discretion to indemnify our other officers and employees when determined appropriate by our board of directors. We expect to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for

related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We also intend to obtain customary directors' and officers' liability insurance upon consummation of this offering.

The limitation of liability and indemnification provisions in our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws to be in effect upon the closing of this offering may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2019.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock awards ($)[1]	Option awards ($)	Nonequity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)[2]	Total ($)
Snehal Patel, *Chief Executive Officer*	2019	—	—	122,750	—	—	—	16,423	139,173

(1) For 2019 fiscal year, Mr. Patel received 148,254 shares of our common stock for services rendered and as incentive for services to be rendered. Mr. Patel did not receive any options or warrants for the 2019 fiscal year.

(2) For fiscal year 2019, Mr. Patel received (i) 4,494,383 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through September 30, 2019 and (ii) 1,656,607 shares of our common stock in exchange for warrants to purchase shares of our common stock.

Outstanding Equity Awards at December 31, 2019

The following table provides information regarding awards held by each of our named executive officers that were outstanding as of December 31, 2019. There were other equity awards outstanding as of December 31, 2019.

	Stock Awards	
Name	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Snehal Patel	600,810[1]	1,347,500

(1) We granted Mr. Patel 749,064 shares of common stock on September 30, 2019 for compensation and incentives of which 93,633 vested immediately upon grant, and the balance, or 655,431 shares of common stock vest over 36 equal monthly installments commencing on October 1, 2019.

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2019. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2019.

Name	Stock awards ($)	All other compensation ($)[4]	Total ($)
David McWilliams[1]	5,249	1,111	6,360
Eric Rothe[2]	3,498	781	4,279
Kenneth Hallock[3]	3,498	1,938	5,436

(1) On September 30, 2019, we authorized the issuance of 28,090 shares of its common stock to Mr. McWilliams. The shares vest in 36 equal monthly installments with the first installment vesting on October 1, 2019. Of such shares, 2,343 shares of common stock vested as of December 31, 2019. Mr. McWilliams did not receive any options or warrants during the 2019 fiscal year.

(2) On September 30, 2019, we authorized the issuance of 18,727 shares of its common stock to Mr. Rothe. The shares vest in 36 equal monthly installments with the first installment vesting on October 1, 2019. Of such shares, 1,563 shares of common stock vested as of December 31, 2019. Mr. Rothe did not receive any options or warrants during the 2019 fiscal year.

(3) On September 30, 2019, we authorized the issuance of 18,727 shares of its common stock to Mr. Hallock. The shares vest in 36 equal monthly installments with the first installment vesting on October 1, 2019. Of such shares, 1,563 shares of common stock vested as of December 31, 2019. Mr. Hallock did not receive any options or warrants during the 2019 fiscal year.

(4) Mr. McWilliams received (i) 149,813 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 266,436 shares of our common stock in exchange for warrants to purchase shares of common stock. Mr. Rothe received (i) 37,454 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 255,005 shares of our common stock in exchange for warrants to purchase shares of common stock. Mr. Hallock received (i) 514,982 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 210,675 shares of our common stock in exchange for warrants to purchase shares of common stock.

Employment Agreements

We intend to enter into employment agreements or consulting agreements with our members of our management upon the consummation of this offering or as soon thereafter as is practicable, including with our Chief Executive Officer as further set forth below.

Snehal Patel Employment Agreement

Upon the closing of the offering contemplated by this registration statement, we will enter into an employment agreement (the "Employment Agreement") with Snehal Patel pursuant to which Mr. Patel will serve as our Chief Executive Officer. The term of the Employment Agreement will continue until December 31, 2021 and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least 60 days prior to the expiration of the then effective term. Pursuant to the terms of the Employment Agreement, Mr. Patel shall, among other things, (i) receive a base salary of $450,000, subject to increase, (ii) shall be eligible to receive equity grants, (iii) shall be eligible to receive an annual bonus of up to 50% of his then base salary and (iv) shall be eligible to receive a strategic transaction bonus. In addition, Mr. Patel shall also be eligible to participate in all employee welfare and benefit plans and shall receive such other fringe benefits as the Company offers to its senior executives and directors.

In the event Mr. Patel's employment is terminated by the Company for Cause (as defined in the Employment Agreement), as a result of Mr. Patel's death or Disability (as defined in the Employment Agreement), voluntarily by Mr. Patel without Good Reason (as defined in the Employment Agreement), or upon expiration of the term, the Company shall pay Mr. Patel (i) a lump sum amount equal to (A) any portion of unpaid base salary and any equity grants then due plus (B) any bonus earned but not paid and (ii) any unpaid expenses (collectively, the "Patel Compensation"). In addition, if Mr. Patel's employment is terminated for death, Disability or as a result of the expiration of the term of the Employment Agreement as a result of the non-renewal of such term by the Company, the Company shall pay Mr. Patel for any pro-rated bonus for the target year in which the termination occurs. In the event Mr. Patel's employment is terminated by the Company without Cause or by Mr. Patel for Good Reason, the Company shall pay Mr. Patel (i) the Patel Compensation, (ii) payment for any pro-rated bonus for the target year in which the termination occurs and (iii) provided that Mr. Patel executes the Release (as defined in the Employment Agreement), (A) the Severance Payment (as defined in the Employment Agreement) and (B) COBRA premiums for twelve months from the date of termination. In the event of Mr. Patel's termination (i) by the Company without Cause or by Mr. Patel for Good Reason within six months prior to the consummation of a Change of Control (as defined in the Employment Agreement) transaction, if, prior to or as of such termination, a Change of Control transaction was Pending (as defined in the Employment Agreement), at any time during such six month period, (ii) by Mr. Patel for Good Reason at any time within twelve months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time within twelve months after the consummation of a Change of Control, Mr. Patel shall receive (A) the Patel Compensation, (B) payment for any pro-rated bonus for the target year in which the termination occurs and (C) provided that Mr. Patel executes the Release, (a) a lump sum amount equal to twelve months of Mr. Patel's then base salary and equity grants at the rate in effect as of the date of termination and (b) COBRA premiums for six months from the date of termination. Furthermore, all of the shares that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Mr. Patel, become fully exercisable for (i) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending but in no event beyond expiration of the original term of the award or (i) if clause (ii) does not apply, then such period of time set forth in the agreement evidencing the security.

The Employment Agreement also contains covenants restricting Mr. Patel from: (i) engaging in any activity competitive with our business during the term of the Employment Agreement and for a period of one year thereafter; and (ii) soliciting our customer, suppliers or employees during the term of the Employment Agreement and for a period of one year thereafter.

2019 Equity Incentive Plan

Summary

Our 2019 Equity Incentive Plan (the "2019 Plan") was adopted by our board of directors on September 30, 2019 and by our stockholders on September 30, 2019. Having an adequate number of shares available for future equity compensation grants is necessary to promote our long-term success and the creation of stockholders value by:

- Enabling us to continue to attract and retain the services of key service providers who would be eligible to receive grants;
- Aligning participants' interests with stockholders' interests through incentives that are based upon the performance of our common stock;
- Motivating participants, through equity incentive awards, to achieve long-term growth in the Company's business, in addition to short-term financial performance; and
- Providing a long-term equity incentive program that is competitive as compared to other companies with whom we compete for talent.

The 2019 Plan permits the discretionary award of incentive stock options ("ISOs"), nonstatutory stock options ("NQSOs"), restricted stock, restricted stock units ("RSUs"), stock appreciation rights ("SARs"), other equity awards and/or cash awards to selected participants. The 2019 Plan will remain in effect until the earlier of (i) September 30, 2029 and (ii) the date upon which the 2019 Plan is terminated pursuant to its terms, and in any event subject to the maximum share limit of the 2019 Plan.

The 2019 Plan provides for the reservation of 1,498,128 shares of common stock for issuance thereunder (the "Share Limit"), and provides that the maximum number of shares that may be issued pursuant to the exercise of ISOs is 1,498,128 (the "ISO Limit"). The number of shares available for issuance under the 2019 Plan constituted approximately 14.47% of our issued and outstanding shares of common stock on a fully diluted basis as of the date of board approval.

Key Features of the 2019 Plan

Certain key features of the 2019 Plan are summarized as follows:

- If not terminated earlier by our board of directors, the 2019 Plan will terminate on September 30, 2029.
- Up to a maximum aggregate of 1,498,128 shares of common stock may be issued under the 2019 Plan. The maximum number of shares that may be issued pursuant to the exercise of ISOs is also 1,498,128.
- The 2019 Plan will generally be administered by a committee comprised solely of independent members of our board of directors. This committee will be the Compensation Committee unless otherwise designated by our board of directors (the "Committee"). The board may designate a separate committee to make awards to employees who are not officers subject to the reporting requirements of Section 16 of the Exchange Act.
- Employees, consultants and board members are eligible to receive awards, provided that the Committee has the discretion to determine (i) who shall receive any awards, and (ii) the terms and conditions of such awards.
- Awards may consist of ISOs, NQSOs, restricted stock, RSUs, SARs, other equity awards and/or cash awards.
- Stock options and SARs may not be granted at a per share exercise price below the fair market value of a share of our common stock on the date of grant.
- Stock options and SARs may not be repriced or exchanged without stockholder approval.

- The maximum exercisable term of stock options and SARs may not exceed ten years.
- Awards are subject to recoupment of compensation policies adopted by us.

Eligibility to Receive Awards. Employees, consultants and our board members and certain of our affiliated companies are eligible to receive awards under the 2019 Plan. The Committee determines, in its discretion, the selected participants who will be granted awards under the 2019 Plan.

Shares Subject to the 2019 Plan. The maximum number of shares of common stock that can be issued under the 2019 Plan is 1,498,128 shares.

The shares underlying forfeited or terminated awards (without payment of consideration), or unexercised awards become available again for issuance under the 2019 Plan. No fractional shares may be issued under the 2019 Plan. No shares will be issued with respect to a participant's award unless applicable tax withholding obligations have been satisfied by the participant.

Administration of the 2019 Plan. The 2019 Plan will be administered by our board's Compensation Committee, acting as the Committee, which shall consist of independent board members. With respect to certain awards issued under the 2019 Plan, the members of the Committee also must be "Non-Employee Directors" under Rule 16b-3 of the Exchange Act. Subject to the terms of the 2019 Plan, the Committee has the sole discretion, among other things, to:

- Select the individuals who will receive awards;
- Determine the terms and conditions of awards (for example, performance conditions, if any, and vesting schedule);
- Correct any defect, supply any omission, or reconcile any inconsistency in the 2019 Plan or any award agreement;
- Accelerate the vesting, extend the post-termination exercise term or waive restrictions of any awards at any time and under such terms and conditions as it deems appropriate, subject to the limitations set forth in the 2019 Plan;
- Permit a participant to defer compensation to be provided by an award; and
- Interpret the provisions of the 2019 Plan and outstanding awards.

The Committee may suspend vesting, settlement, or exercise of awards pending a determination of whether a selected participant's service should be terminated for cause (in which case outstanding awards would be forfeited). Awards may be subject to any policy that the board may implement on the recoupment of compensation (referred to as a "clawback" policy). The members of the board, the Committee and their delegates shall be indemnified by us to the maximum extent permitted by applicable law for actions taken or not taken regarding the 2019 Plan. In addition, the Committee may use the 2019 Plan to issue shares under other plans or sub-plans as may be deemed necessary or appropriate, such as to provide for participation by non-U.S. employees and those of any of our subsidiaries and affiliates.

Types of Awards.

Stock Options. A stock option is the right to acquire shares at a fixed exercise price over a fixed period of time. The Committee will determine, among other terms and conditions, the number of shares covered by each stock option and the exercise price of the shares subject to each stock option, but such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant of the stock option. The exercise price of each stock option granted under the 2019 Plan must be paid in full at the time of exercise, either with cash, or through a broker-assisted "cashless" exercise and sale program, or net exercise, or through another method approved by the Committee. Stock options granted under the 2019 Plan may be either ISOs or NQSOs. In order to comply with Treasury Regulation Section 1.422-2(b), the 2019 Plan provides that no more than 1,498,128 shares may be issued pursuant to the exercise of ISOs.

SARs. A SAR is the right to receive, upon exercise, an amount equal to the difference between the fair market value of the shares on the date of the SAR's exercise and the aggregate exercise price of the shares covered by the exercised portion of the SAR. The Committee determines the terms of SARs, including the exercise price (provided

that such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant), the vesting and the term of the SAR. Settlement of a SAR may be in shares of common stock or in cash, or any combination thereof, as the Committee may determine. SARs may not be repriced or exchanged without stockholder approval.

Restricted Stock. A restricted stock award is the grant of shares of our common stock to a selected participant and such shares may be subject to a substantial risk of forfeiture until specific conditions or goals are met. The restricted shares may be issued with or without cash consideration being paid by the selected participant as determined by the Committee. The Committee also will determine any other terms and conditions of an award of restricted stock.

RSUs. RSUs are the right to receive an amount equal to the fair market value of the shares covered by the RSU at some future date after the grant. The Committee will determine all of the terms and conditions of an award of RSUs. Payment for vested RSUs may be in shares of common stock or in cash, or any combination thereof, as the Committee may determine. RSUs represent an unfunded and unsecured obligation for us, and a holder of a stock unit has no rights other than those of a general creditor.

Other Awards. The 2019 Plan also provides that other equity awards, which derive their value from the value of our shares or from increases in the value of our shares, may be granted. In addition, cash awards may also be issued. Substitute awards may be issued under the 2019 Plan in assumption of or substitution for or exchange for awards previously granted by an entity which we (or an affiliate) acquire.

Limited Transferability of Awards. Awards granted under the 2019 Plan generally are not transferrable other than by will or by the laws of descent and distribution. However, the Committee may in its discretion permit the transfer of awards other than ISOs.

Change in Control. In the event that we are a party to a merger or other reorganization or similar transaction, outstanding 2019 Plan awards will be subject to the agreement pertaining to such merger or reorganization. Such agreement may provide for (i) the continuation of the outstanding awards by us if we are a surviving corporation, (ii) the assumption or substitution of the outstanding awards by the surviving entity or its parent, (iii) full exercisability and/or full vesting of outstanding awards, or (iv) cancellation of outstanding awards either with or without consideration, in all cases with or without consent of the selected participant. The Committee will decide the effect of a change in control of us on outstanding awards.

Amendment and Termination of the 2019 Plan. The board generally may amend or terminate the 2019 Plan at any time and for any reason, except that it must obtain stockholder approval of material amendments to the extent required by applicable laws, regulations or rules.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2018 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this prospectus. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

On October 9, 2019, Eric Rothe, a director, loaned us $15,000 which is payable on demand, is not secured, and does not incur interest, all of which remains outstanding as of June 15, 2020.

On May 30, 2018 and October 2, 2019, the Kenneth and Annette Hallock Revocable Trust loaned us $100,000 and $200,000, respectively, which is payable on demand, is not secured, and does not incur interest, all of which remains outstanding as of June 15, 2020. Kenneth Hallock, a director, is one of the Trustees of the Hallock Trust.

Between November 2014 and August 2017, Snehal Patel, our Chief Executive Officer and director, loaned us an aggregate of $320,154, which is payable on demand, is not secured, and does not incur interest, all of which remains outstanding as of June 15, 2020. In addition, as of December 31, 2019, Snehal Patel is owed $4,817 for reimbursable expenses.

On August 19, 2019, all plague vaccine assets, including our intellectual property and know-how, which as of the date of transfer could not be developed and had zero value to us due to dormancy and termination of the plague vaccine research program in 2016, were transferred to Snehal Patel at zero value in consideration for a 0.5% royalty payment due and payable to us on the first year of net sales in the event the plague vaccine assets are commercialized. No additional royalties shall be due and payable to us after the first year of net sales.

As of September 30, 2019, related party payables to our officers and directors since January1, 2010 totaled $12 million. As of September 30, 2019, our officers and directors owned outstanding warrants to acquire 2,565,521 shares of our common stock. On September 30, 2019, the officers and directors exchanged all related party payables and outstanding warrants for an aggregate of 7,902,603 shares of our common stock, leaving us with no related party payables and no outstanding warrants on September 30, 2019.

Indemnification Agreements

In connection with this offering, we entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Delaware law. See “Description of Share Capital — Indemnification of Directors and Officers” for additional information regarding indemnification under Delaware law and our amended and restated by-laws.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. Upon consummation of this offering, we shall adopt a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of June 15, 2020 by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of June 15, 2020, pursuant to the exercise of options or warrants, vesting of common stock or conversion of preferred stock or convertible debt, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 10,593,555 shares of common stock issued and outstanding as of June 15, 2020 assuming the conversion of all outstanding shares of preferred stock.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Greenwich LifeSciences, Inc., 3992 Bluebonnet Dr, Building 14, Stafford, TX 77477.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Common Stock Beneficially Owned	
		Before Offering	After Offering
Directors and Named Executive Officers			
Snehal Patel	7,162,968 (1)	67.38%	61.59%
F. Joseph Daugherty	38,758 (2)	*	*
David McWilliams	595,440 (3)	5.62%	5.14%
Eric Rothe	298,230 (4)	2.81%	2.57%
Kenneth Hallock	286,165 (5)	2.70%	2.47%
All current named executive officers and directors as a group (5 persons)	8,381,561	78.79%	72.02%
5% or Greater Stockholders			
Pankaj Patel	1,123,596 (6)	10.61%	9.69%
Jim Hallock	561,798 (7)	5.30%	4.85%

* Represents beneficial ownership of less than one percent (1%).

(1) Consists of (i) 294,182 shares of common stock owned by Snehal Patel, (ii) 176,798 shares of common stock owned by Snehal Patel IRA, (iii) 2,405,670 shares of common stock owned by Patel Family Trust 1, (iv) 1,320,226 shares of common stock owned by Patel Family Trust 2, (v) 1,329,590 shares of common stock owned by Patel Family Trust 3, (vi) 176,448 shares of common stock underlying shares of Series A Preferred Stock owned by Snehal Patel, (vii) 1,144,529 shares of common stock underlying shares of Series A Preferred Stock owned by Snehal Patel IRA, (viii) 13,736 shares of common stock underlying shares of Series B Preferred Stock owned by Snehal Patel, (ix) 76,780 shares of common stock underlying shares of Series B Preferred Stock owned by Kinnary Patel IRA, (x) 2,997 shares of common stock underlying shares of Series B Preferred Stock owned by Snehal Patel IRA, (xi) 10,394 shares of common stock underlying shares of Series C Preferred Stock owned by Snehal Patel, (xii) 33,708 shares of common stock underlying shares of Series C Preferred Stock owned by Snehal Patel IRA, (xiii) 89,510 shares of common stock underlying shares of Series D Preferred Stock owned by Snehal Patel, (xiv) 45,328 shares of common stock underlying shares of Series D Preferred Stock owned by Kinnary Patel IRA and (xv) 43,072 shares of common stock underlying shares of Series D Preferred Stock owned by Snehal Patel IRA. Excludes 455,154 shares of common stock held by Snehal Patel which vest in 25 equal monthly installments. Snehal Patel and Kinnary Patel, the spouse of Snehal Patel, are the Trustees of the Patel Family Trust 1, Patel Family Trust 2 and Patel Family Trust 3. Snehal Patel is the Trustee of the Snehal Patel IRA. Kinnary Patel is the Trustee of the Kinnary Patel IRA. In such capacities, Snehal Patel is deemed to hold voting and dispositive power over the securities held by such entities.

(2) Excludes 45,513 shares of common stock which vest in 25 equal monthly installments.

(3) Consists of (i) 424,872 shares of common stock, (ii) 152,604 shares of common stock underlying shares of Series A Preferred Stock, (iii) 7,663 shares of common stock underlying shares of Series B Preferred Stock, (iv) 3,746 shares of common stock underlying shares of Series C Preferred Stock and (v) 6,555 shares of common stock underlying shares of Series D Preferred Stock. Excludes 19,499 shares of common stock which vest in 25 equal installments.

(4) Excludes 12,996 shares of common stock which vest in 25 equal monthly installments.

(5) Consists of (i) 169,590 shares of common stock owned by the Kenneth and Annette Hallock Revocable Trust (the "Hallock Trust"), (ii) 18,727 shares of common stock underlying shares of Series B Preferred Stock owned by the Hallock Trust, (iii) 18,727 shares of common stock underlying shares of Series C Preferred Stock owned by the Hallock Trust and (iv) 79,121 shares of common stock underlying shares of Series D Preferred Stock owned by the Hallock Trust. Excludes 12,996 shares of common stock which vest in 25 equal monthly installments. Kenneth Hallock and Annette Hallock are the Trustees of the Hallock Trust and in such capacities share voting and dispositive power over the securities held by such entity.

(6) Consists of (i) 187,266 shares of common stock owned by the Yosajo MI Trust 1, (ii) 187,266 shares of common stock owned by the Yosajo MI Trust 2, (iii) 187,266 shares of common stock owned by the Yosajo MI Trust 3, (iv) 187,266 shares of common stock owned by the Yosajo MA Trust 1, (v) 187,266 shares of common stock owned by the Yosajo MA Trust 2 and (vi) 187,266 shares of common stock owned by the Yosajo MA Trust 3. Pankaj Patel is the Trustee of the foregoing trusts and in such capacity has the right to vote and dispose of the securities held by such trusts.

(7) Consists of (i) 187,266 shares of common stock owned by the Brent Thomas Henderson 2010 Trust, (ii) 187,266 shares of common stock owned by the David Brian Henderson 2010 Trust and (iii) 187,266 shares of common stock owned by the Thatcher Duncan Hallock 2010 Trust. Jim Hallock is the Trustee of the foregoing trusts and in such capacity has the right to vote and dispose of the securities held by such trusts.

DESCRIPTION OF CAPITAL STOCK

General

Upon completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

As of June 15, 2020, there were 25 record holders of our securities. As of June15, 2020 there were 8,613,190 shares of common stock issued and outstanding. In addition, as of June15, 2020, 1,520,937 shares of Series A Preferred Stock, 129,267 shares of Series B Preferred Stock, 66,575 shares of Series C Preferred Stock and 263,586 shares of Series D Preferred Stock were issued and outstanding which shares of preferred stock are convertible into an aggregate of 1,980,365 shares of common stock upon closing of this offering.

The following description of our capital stock and provisions of our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws to be effective upon the completion of this offering is only a summary. You should also refer to our Second Amended and Restated Certificate of Incorporation, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part, and our Second Amended and Restated Bylaws, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part.

Common Stock

We are authorized to issue up to a total of 100,000,000 shares of common stock, par value $0.001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights.

Further, holders of our common stock have no preemptive or conversion rights or other subscription rights. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available. Each outstanding share of our common stock is, and all shares of common stock to be issued in this offering when they are paid for will be, fully paid and non-assessable.

The holders of a majority of the shares of our capital stock, represented in person or by proxy, are necessary to constitute a quorum for the transaction of business at any meeting. If a quorum is present, an action by stockholders entitled to vote on a matter is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, with the exception of the election of directors, which requires a plurality of the votes cast.

Preferred Stock

Our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, will be able to issue convertible preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock. At present, we have no plans to issue any shares of preferred stock following this offering.

Options

Our 2019 Equity Incentive Plan provides for us to sell or issue shares restricted shares of common stock, or to grant incentive stock options or nonqualified stock options, stock appreciation rights and restricted stock unit awards for the purchase of shares of common stock, to employees, members of the board of directors and consultants. As of June 15, 2020, no options to purchase common shares were outstanding. For additional information regarding the terms of the 2019 Plan, see “Executive and Director Compensation — 2019 Equity Incentive Plan.”

Registration Rights Agreement

We have granted holders of our Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock registration rights pursuant to which we have agreed to, among other things, file with the SEC a registration statement under the Securities Act that covers the resale of shares of common stock issuable upon conversion of such preferred stock (the "Conversion Shares") and any shares of common stock issued as a dividend or other distribution with respect to, in exchange for, or in replacement of such Conversion Shares (collectively, the "Registrable Securities"). Specifically, holders of at least a majority of the Registrable Securities may request that we file a registration statement covering the Registrable Securities. In addition, subject to certain exceptions, in the event we propose to register any of our securities in connection with a public offering, the holders of Registrable Securities may request such that such Registrable Securities be included in such registration statement. The registration rights shall terminate (i) three years after the closing date of this offering and (ii) as to any holder, at such time following this offering, as all Registrable Securities that such holder holds or has the right to acquire may be sold in any three month period pursuant to Rule 144 under the Securities Act.

Exclusive Forum

Our Amended and Restated Bylaws to be effective upon completion of this offering provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the DGCL or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws to be effective upon completion of this offering, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction.

Additionally, our Amended and Restated Bylaws to be effective upon completion of this offering provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision.

Anti-Takeover Provisions of Delaware Law, our Second Amended and Restated Certificate of Incorporation and our Second Amended and Restated Bylaws

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly traded Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation's voting stock, subject to certain exceptions. The statute could have the effect of delaying, deferring or preventing a change in control of our Company.

Board of Directors Vacancies

Our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution of the majority of the incumbent directors.

Stockholder Action; Special Meeting of Stockholders

Our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws provide that our stockholders may not take action by written consent. Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws further provide that special meetings of our stockholders may be called by a majority of the board of directors, the Chief Executive Officer, or the Chairman of the board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Second Amended and Restated Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise. If we issue such shares without stockholder approval and in violation of limitations imposed by The Nasdaq Capital Market or any stock exchange on which our stock may then be trading, our stock could be delisted.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, Inc.

Stock Market Listing

We have applied to have our shares of common stock listed for trading on The Nasdaq Capital Market under the symbol "GLSI." No assurance can be given that such listing will be approved.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time, and could impair our ability to raise capital through sales of equity or equity-related securities.

Only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we have applied to list our common stock on The Nasdaq Capital Market, we cannot assure you that there will be an active market for our common stock.

Of the shares to be outstanding immediately after the completion of this offering, we expect that the shares to be sold in this offering and the shares of common stock sold by the selling stockholders will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Certain of the remaining shares of our common stock outstanding after this offering will be subject to a 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our common stock in the public market, whether or not those shares are "restricted securities." "Restricted securities" are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our common stock issued prior to the closing of the offering made hereby, are considered to be restricted securities. The shares of our common stock sold in this offering are not considered to be restricted securities.

Non-Affiliate Resales of Restricted Securities

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our common stock. Subject to the lock-up agreements described below, those persons may sell shares of our common stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our common stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our common stock for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our common stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144, described above.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144.

Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the 180-day lock-up period described below.

Equity Incentive Awards

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this offering to register the shares of common stock that are issuable pursuant to our Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangement described above, if applicable.

Lock-Up & Leak Out Agreements

Each of our directors and executive officers and certain holders of our outstanding securities prior to this offering have entered into a lock-up/leak-out agreement (the "Lock-Up/Leak-Out Agreement") with us pursuant to which such officers, directors and stockholders have agreed to not sell their securities during such period commencing upon the date of the filing of this registration statement and ending at such time as may be determined by the underwriters in this offering; provided, however, that such lock-up period shall not end later than 180 days from the effective date of this registration statement. In addition, such officers, directors and shareholders have agreed that for a period of 48 months following the completion of the Company's initial public offering they shall not transfer, sell, contract to sell, devise, gift, assign, pledge, hypothecate, distribute or grant any option to purchase or otherwise dispose of, directly or indirectly, any of their shares subject to the Lock-Up/Leak-Out Agreement; provided, however, our Board of Directors may, in its sole discretion, amend the terms of the Lock-Up/Leak-Out Agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended("Internal Revenue Code") Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to our operations or to the purchase, ownership or disposition of our shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the U.S. (for U.S. federal income tax purposes);

- a corporation or other entity taxable as a corporation created or organized in the U.S. or under the laws of the U.S., any state thereof, or the District of Columbia, or other entity treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

Distributions

As described in "Dividend Policy," we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "— Gain on Disposition of Common Stock."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the U.S.) are generally exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the U.S.);

- you are a non-resident alien individual who is present in the U.S. for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or

- our common stock constitutes a U.S. real property interest by reason of our status as a "U.S. real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding your disposition of our common stock, or (ii) your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the U.S. (as defined for U.S. federal estate tax purposes) at the time of their death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the U.S. for U.S. federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be non-U.S. holders for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to "foreign financial institutions" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well

as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. An intergovernmental agreement between the U.S. and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

Aegis Capital Corp. ("Aegis") is acting as the representative of the underwriters and the book-running manager of this offering. Under the terms of an underwriting agreement, which is filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the respective number of shares of common stock shown opposite its name below:

Underwriters	Number of Shares
Aegis Capital Corp.	

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

Commissions and Expenses

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total with no Over-Allotment	Total with Over-Allotment
Public offering price	$	$	$
Underwriting discount (7%)	$	$	$
Non-accountable expense allowance (1%)[1]	$	$	$
Proceeds, before expenses, to us	$	$	$

_____

(1) We have agreed to pay a non-accountable expense allowance to the representative equal to 1.0% of the gross proceeds received in this offering.

We have paid an advance of $50,000 to the representative, which will be applied against actual out-of-pocket accountable expenses and reimbursed to the Company to the extent any portion thereof is not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

The representative has advised us that the underwriters propose to offer the shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of $ per share. After the offering, the representatives may change the offering price and other selling terms.

The expenses of this offering that are payable by us are estimated to be approximately $607,075 (excluding estimated underwriting discounts and commissions). We have also agreed to reimburse the underwriters for certain of their expenses, in an amount up to $100,000, including for road show, diligence, and reasonable legal fees, as set forth in the underwriting agreement.

Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for 45 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price less underwriting discounts and commissions. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in this offering as indicated in the table at the beginning of this Underwriting Section.

Lock-Up Agreements

We, all of our directors and executive officers have agreed that, for a period of 180 days after the date of this prospectus subject to certain limited exceptions, we and they will not directly or indirectly, without the prior written consent of Aegis, (i) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock, (ii) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (iii) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any of our other securities, or (iv) publicly disclose the intention to do any of the foregoing.

Aegis, in its sole discretion, may release the common stock and other securities subject to the lockup agreements described above in whole or in part at any time. When determining whether or not to release common stock and other securities from lock-up agreements, Aegis will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

Underwriter's Warrants

We have also agreed to issue to the representative or its designees, at the closing of this offering, warrants (the "Underwriter's Warrants") to purchase shares of common stock (8% of the number of shares sold in the offering, excluding the over-allotment option). The Underwriter's Warrants will be exercisable at any time and from time to time, in whole or in part, during a period commencing six months from the effective date of this offering and expiring five years from the effective date of the offering. The Underwriter's Warrants will be exercisable at a price equal to 125% of the public offering price per share of common stock and such warrants shall be exercisable on a cash basis, provided that if a registration statement registering the common stock underlying the Underwriter's Warrants is not effective, the Underwriter's Warrants may be exercised on a cashless basis. If the Underwriter's Warrants are exercised for cash within the first six months of the period in which they are exercisable, the exercise price will be equal to 97% of 125% of the public offering price. The Underwriter's Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180 -day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative or its permitted assignees under this Rule 5110(g)(1) shall not sell, transfer, assign, pledge or hypothecate the Underwriter's Warrants, nor engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Underwriter's Warrants, for a period of 180 days from the effective date of the offering, except that they may be assigned, in whole or in part, as specifically set forth in the underwriting agreement. The Underwriter's Warrants will provide for customary anti-dilution provisions (for stock dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110, and the number of shares underlying the Underwriter's Warrants shall be reduced, or the exercise price increased, if necessary, to comply with FINRA rules or regulations. Further, the Underwriter's Warrants will provide for a one -time demand registration right and unlimited piggyback rights. The Underwriter's Warrants and underlying shares are included in this prospectus.

Right of First Refusal

Pursuant to the terms of the underwriting agreement, Aegis shall have the right of first refusal for a period of nine months after the closing of this offering to act as sole book-running manager for all future public equity offerings by us, or any successor to or subsidiary of our Company, during such period.

Offering Price Determination

Prior to this offering, there has been no public market for our common stock. The initial public offering price was negotiated between the representative and us. In determining the initial public offering price of our common stock, the representative considered:

- the history and prospects for the industry in which we compete;
- our financial information;
- the ability of our management and our business potential and earning prospects;
- the prevailing securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Stabilization, Short Positions and Penalty Bids

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

Listing on The Nasdaq Capital Market

We have applied to have our common stock listed on The Nasdaq Capital Market under the symbol "GLSI."

Discretionary Sales

The underwriters have informed us that they do not expect to sell more than 5% of the common stock in the aggregate to accounts over which they exercise discretionary authority.

Other Relationships

Certain of the underwriters and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they may in the future receive customary fees.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Sichenzia Ross Ference LLP, New York, New York.

EXPERTS

The financial statements of Greenwich LifeSciences, Inc. as of December31, 2019 and 2018 and for each of the years then ended included in this Registration Statement, of which this prospectus forms a part, have been so included in reliance on the report of MaloneBailey, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

The registration statement is available at the Securities and Exchange Commission's website at*www.sec.gov*. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, accordingly, will be required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to inspect and copy such periodic reports, proxy statements and other information at the website of the Securities and Exchange Commission referred to above.

GREENWICH LIFESCIENCES, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Greenwich LifeSciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Greenwich LifeSciences, Inc. (the "Company") as of December 31, 2019 and 2018, and the related statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2019.
Houston, Texas
April 2, 2020, except for Note 8, which is dated June 22, 2020

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2019 AND 2018

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash	$ 6,835	$ 85,102
Total current assets	6,835	85,102
Acquired patents, net	19,836	23,443
Total assets	$ 26,671	$ 108,545
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable & accrued interest	$ 730,309	$ 277,556
Unreimbursed expenses	11,626	30,889
Advance from related party/shareholder	635,154	420,154
Total current liabilities	1,377,089	728,599
Related party payable	—	9,500,000
Total liabilities	1,377,089	10,228,599
Stockholders' deficit		
Common stock, $0.001 par value; 100,000,000 shares authorized; 8,458,048 and 202,996 shares issued and outstanding as of December 31, 2019 and 2018, respectively	8,458	203
Preferred stock, $0.001 par value; 6,795,000 shares authorized;		
Series A preferred stock: 1,520,937 issued and outstanding as of December 31, 2019 and 2018	1,521	1,521
Series B preferred stock: 129,267 issued and outstanding as of December 31, 2019 and 2018	129	129
Series C preferred stock: 66,575 issued and outstanding as of December 31, 2019 and 2018	67	67
Series D preferred stock: 263,586 issued and outstanding as of December 31, 2019 and 2018, respectively	264	264
Additional paid-in capital	25,853,134	13,666,446
Accumulated deficit	(27,213,991)	(23,788,684)
Total stockholders' deficit	(1,350,418)	(10,120,054)
Total liabilities and stockholders' deficit	$ 26,671	$ 108,545

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Year Ended December 31,	
	2019	**2018**
Revenue	$ —	$ —
Operating expenses		
Research and development	2,606,420	1,270,016
General and administrative	818,887	419,639
Total operating expenses	3,425,307	1,689,655
Loss from operations	(3,425,307)	(1,689,655)
Net loss	$ (3,425,307)	$ (1,689,655)
Per share information:		
Net loss per common share, basic and diluted	$ (1.52)	$ (8.32)
Weighted average common shares outstanding, basic and diluted	2,257,979	202,996

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Amount	Shares	Par Amount			
Balances, December 31, 2017	202,996	$ 203	1,961,638	$ 1,962	$ 13,566,465	$ (22,099,029)	$ (8,530,399)
Preferred Stock Sold	—	—	18,727	19	99,981	—	100,000
Net loss						(1,689,655)	(1,689,655)
Balances, December 31, 2018	202,996	203	1,980,365	1,981	13,666,446	(23,788,684)	(10,120,054)
Exchange of related party payables and warrants for common stock	8,012,684	8,013	—	—	11,991,987	—	12,000,000
Stock-based compensation	242,368	242	—	—	194,701	—	194,943
Net loss						(3,425,307)	(3,425,307)
Balances, December 31, 2019	8,458,048	$ 8,458	1,980,365	$ 1,981	$ 25,853,134	$ (27,213,991)	$ (1,350,418)

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER31, 2019 AND 2018

	Year Ended December 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (3,425,307)	$ (1,689,655)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	3,607	3,607
Stock-based compensation	194,943	—
Changes in operating assets and liabilities:		
Accounts payable	393,402	80,967
Accrued interest	59,353	35,442
Unreimbursed expenses (accrued)	(19,263)	(45,313)
Related party payable	2,500,000	1,500,000
Net cash used in operating activities	(293,267)	(114,952)
Investing activities:		
Financing activities:		
Proceeds/repurchase of preferred stock	—	100,000
Advance from related party/shareholder	215,000	100,000
Net cash provided by (used in) financing activities	215,000	200,000
Net increase (decrease) in cash	(78,267)	85,048
Cash, beginning of period	85,102	54
Cash, end of period	$ 6,835	$ 85,102
Non-cash investing and financing activities:		
Common stock to settle related party payable	12,000,000	

See accompanied notes to financial statements.

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. Going Concern

The Company has prepared its financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

As of December 31, 2019, the Company had cash of $6,835. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

3. Significant Accounting Policies

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of US Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in its financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Cash

Cash consists primarily of deposits with commercial banks and financial institutions.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded through December 31, 2019.

Stock-Based Compensation

Compensation expense related to warrants and stock granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on a straight-line basis over the requisite service period. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

3. Significant Accounting Policies (cont.)

Research and Development Costs

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, salaries, costs of outside collaborators and outside services, and supplies.

Income Taxes

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of tax liabilities involves dealing with uncertainties in the application of complex tax regulations.

Basic and Diluted Loss per Share

The Company computes loss per share in accordance with Accounting Standards Codification ("ASC") 260 — Earnings per Share. ASC 260 requires presentation of both basic and diluted earnings per share ("EPS") on the face of the statements of operations. Basic EPS is computed by dividing net loss available to common shareholders (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 and convertible notes payable using the if-converted method. Diluted EPS excludes all dilutive potential shares if their effect is antidilutive. During periods of net loss, all common stock equivalents are excluded from the diluted EPS calculation because they are antidilutive.

As of December 31, 2019 and 2018, the Company has 1,520,937 shares of the Company's common stock issuable upon conversion of the Company's Series A Preferred Stock, 129,267 shares of the Company's common stock issuable upon conversion of the Company's Series B Preferred Stock, 66,575 shares of the Company's common stock issuable upon conversion of the Company's Series C Preferred Stock, and 263,586 shares of the Company's common stock issuable upon conversion of the Company's Series D Preferred Stock.

As of December 31, 2019 the company has no warrants and as of December 31, 2018, the Company has common stock equivalents related to warrants outstanding to acquire 2,675,602 shares of the Company's common stock.

Recent Accounting Pronouncements

The Company has evaluated the following recent accounting pronouncements through the date the financial statements were issued and filed with the SEC and believes that none of them will have a material effect on the Company's financial statements:

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases: Topic 842 (ASU 2016-02)", to supersede nearly all existing lease guidance under GAAP. The guidance would require lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets. ASU 2016-02 is effective for the Company in the first quarter of its fiscal year ending December 31, 2019 using a modified retrospective approach with the option to elect certain practical expedients. The Company has no leases, thus the adoption of ASU 2016-02 will have no material impact on the Company's financial statements.

In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts from Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. The amendments in this update affect the guidance in ASU 2014-09. The core principle of the guidance in Topic 606 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendments in ASU 2016-12 do not change the core principle of the guidance in Topic 606, but instead affect only the narrow aspects noted in Topic 606. Topic 606 became effective for the Company on December 1, 2018. The Company has no revenue, thus the adoption of ASU 2016-12 will have no material impact on the Company's financial statements.

3. Significant Accounting Policies (cont.)

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The Company has elected early adoption of ASU 2017-09 to conform the accounting for share-based compensation to employees and nonemployees.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company evaluated ASU 2017-11 and determined that the adoption of this new accounting standard did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," which modifies the accounting for share-based payment awards issued to nonemployees to largely align it with the accounting for share-based payment awards issued to employees. ASU 2018-07 is effective for us for annual periods beginning January 1, 2019. The Company evaluated ASU 2018-07 and determined that the adoption of this new accounting standard did not have a material impact on the Company's financial statements.

4. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total $11,626 as of December 31, 2019 and $30,889 as of December 31, 2018. In October 2019, the Kenneth Hallock and Annette Hallock Revocable Trust loaned $200,000 to the Company and Eric Rothe, a director of the Company, loaned $15,000 to the Company, both of which are payable on demand, are not secured, and do not incur interest. Kenneth Hallock, a director of the Company, is one of the Trustees of the Hallock Trust. In 2018, the Kenneth Hallock and Annette Hallock Revocable Trust loaned $100,000 to the Company that is payable on demand, not secured, and does not incur interest. In total, Snehal Patel, Company's Chief Executive Officer and director, Eric Rothe, and the Kenneth Hallock and Annette Hallock Revocable Trust have loaned capital to the Company that is payable on demand, is not secured, and does not incur interest, which in the aggregate totals $635,154 as of December 31, 2019 and $420,154 as of December 31, 2018.

4. Related Party Transactions (cont.)

Related party payables to the Company's officers and directors since January 1, 2010 total $12.0 million as of September 30, 2019 and $9.5 million as of December 31, 2018. Related party payables were decreased from $12.0 million to $0 and all of the Company's 2,675,602 warrants were cancelled on September 30, 2019, as all related party payables and all warrants were exchanged for an aggregate of 8,012,684 shares of the Company's common stock on September 30, 2019.

5. Income Taxes

Significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
	2019	**2018**
Deferred tax assets:		
Net operating loss carryforwards	790,333	596,018
Valuation allowance	(790,333)	(596,018)
Total deferred tax assets	—	—

The federal income tax rate used for 2019 and 2018 was 21%. At December31, 2019, the Company had federal net operating loss ("NOL") carryforwards of approximately $3.8 million that will expire in tax years up through 2037. The NOLs generated in tax years 2018 and forward will carry forward indefinitely, but the deductibility of such federal net operating losses is limited. The NOL and tax credit carryforwards may be further subject to the application of Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as discussed further below. The Company has provided a valuation allowance to offset the deferred tax assets due to the uncertainty of realizing the benefits of the net deferred tax asset.

The Company's issuances of common and preferred stock have likely resulted in ownership changes as defined by Section 382 of the Code; however, the Company has not conducted a Section 382 study to date. It is possible that a future analysis may result in the conclusion that a substantial portion, or perhaps substantially all of the Company's NOL carryforwards and R&D tax credit carryforwards will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of the carryforwards may be limited and a portion of the carryforwards may expire unused.

The Company is subject to U.S. federal tax examinations by tax authorities for the years 2010 to 2009 due to the fact that NOL carryforwards exist going back to 2010 that may be utilized on a current or future year tax return.

6. Commitments and Contingencies

License Obligation 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 patent and license obligations to HJF, including accrued interest, plus accrued expenses for manufacturing of GP2 for the upcoming Phase III clinical trial through purchase orders with Polypeptide Laboratories and Stratum Medical, which total $730,309 as of December 31, 2019 and $277,556 as of December 31, 2018.

6. Commitments and Contingencies (cont.)

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.

7. Stockholders' Deficit

In 2019, an aggregate total of 8,255,052 shares of the Company's common stock were issued to retire all related party payables, to cancel all warrants, and to compensate and incentivize management, directors, and consultants.

On September 30, 2019, the board of directors (the "Board") and stockholders of the Company adopted the Greenwich LifeSciences, Inc. 2019 Equity Incentive Plan setting aside and reserving 1,498,128 shares of common stock without any issuance of common stock or options under the plan. In addition, on September 30, 2019, the Board authorized the Company to enter into a lock-up/leak-out agreement with its shareholders, the size of the Board was increased from three to five members, two new members were appointed to the Board, $12 million of related party payables and 2,675,602 warrants were exchanged for 8,012,684 shares of the Company's common stock, and 155,433 shares of the Company's common stock were issued upfront at no value in consideration for services and 908,242 shares of the Company's common stock were authorized to be issued at $2,037,000 value based on various vesting schedules that start monthly vesting on October 1, 2019 and on the first day of each subsequent month.

As of December 31, 2019, 77,571 shares of the 908,242 shares of the common stock grant has vested at $173,943 value and 830,671 shares remain unvested and unrecognized at $1,863,057 value.

On December 30, 2019, the Company issued a consultant 9,364 shares of the Company's common stock for services rendered at $21,000 value.

Pursuant to ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," the Company's warrants were valued using the Black-Scholes option pricing model. Assumptions used in the valuation include the following: a) market value of stock on measurement date of $0.00; b) risk-free rate of 0.49%; c) volatility factor of 109%; d) dividend yield of 0.00%. Based on the valuation, the warrants had no value on the grant date of September 30, 2019.

In addition, the Company modified the exercise price of all 2,675,602 warrants to $0 on the modification date of September 30, 2019, and thus the Company exchanged the 2,675,602 warrants for 2,675,602 shares of the Company's common stock at no value on the modification date. The warrants were valued using the Black-Scholes option pricing model. Assumptions used in the valuation include the following: a) market value of stock on measurement date of $0.00; b) risk-free rate of 0.49%; c) volatility factor of 109%; d) dividend yield of 0.00%. Based on the valuation, the modified warrants had no value on the modification date of September 30, 2019. Therefore, no incremental expense was recorded due to the modification.

No new equity was raised in 2019 and 2018, except for the transfer of preferred stock from one custodian to another which included the final transaction for the purchase of 18,727 shares of Series D Preferred Stock from a custodian in 2018 at the original issuance price of $5.34 per share.

As of December 31, 2019, the Company has 1,520,937 shares of Series A Preferred Stock issued and outstanding with a purchase price and conversion price of $0.267 per share.

7. Stockholders' Deficit (cont.)

As of December 31, 2019, the Company has 129,267 shares of Series B Preferred Stock issued and outstanding with a purchase price and conversion price of $1.335 per share with anti-dilution protection of 50% of the subsequent round price if a subsequent round is priced at or below $2.67 per share and a floor of $0.534 per share to limit the anti-dilution protection.

As of December 31, 2019, the Company has 66,575 shares of Series C Preferred Stock issued and outstanding with a purchase price and conversion price of $2.67 per share with anti-dilution protection of 66.7% of the subsequent round price if a subsequent round is priced at or below $4.005 per share and a floor of $0.801 per share to limit the anti-dilution protection.

As of December 31, 2019, the Company has 263,586 shares of Series D Preferred Stock issued and outstanding with a purchase price and conversion price of $5.34 per share with anti-dilution protection of 80% of the subsequent round price if a subsequent round is priced at or below $6.675 per share and a floor of $0.801 per share to limit the anti-dilution protection.

The Series A Preferred Stock has liquidation preference over the Series B Preferred Stock, which has liquidation preference over the Series C Preferred Stock, which has liquidation preference over the Series D Preferred Stock. The holders of preferred stock shall be entitled to receive dividends, on a pari passu basis with the common stock, when, as and if dividends are declared by the Company's board of directors. Each holder of preferred stock shall be entitled to a number of votes equal to the number of whole shares of common stock into which such holder's shares of preferred stock could then be converted and shall have voting rights and powers equal to the voting rights and powers of the common stock. Each share of preferred stock shall automatically be converted into fully paid and nonassessable shares of common stock, at the then effective conversion price, (i) upon the vote, written consent, or conversion of the holders of at least a majority of the issued and outstanding shares of that series of preferred stock, (ii) the closing of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock, or (iii) upon the merger of the Company with an entity whose shares of common stock trade publicly.

Warrants

No new warrants were granted in 2019 and 2018. At December 31, 2018, outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities, are as follows:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
302,256	$ 0.27	July 27, 2020
155,433	$ 1.34	September 20, 2020
159,085	$ 2.67	September 30, 2020
592,700	$ 5.34	June 30, 2021
604,703	$ 5.34	June 30, 2022
262,173	$ 5.34	June 30, 2023
280,899	$ 5.34	June 30, 2024
318,353	$ 5.34	June 30, 2025
2,675,602		

The weighted average exercise price of outstanding warrants to purchase common stock at December 31, 2018 was $4.38 per share with remaining terms expiring between July 27, 2020 to June 30, 2025.

As of December 31, 2019 there are no outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities.

Shares Underlying Outstanding Warrants as of December 31, 2018	Shares Underlying Warrants Exchanged on September 30, 2019	Shares Underlying Outstanding Warrants as of December 31, 2019
2,675,602	(2,675,602)	—

8. Subsequent Events

On June 22, 2020, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effectuate a 1-for-2.67 reverse stock split of the Company's issued and outstanding common and preferred stock. No fractional shares were issued and any fractional shares resulting from the stock split were rounded up to the nearest whole share. All common and preferred stock share and per-share data and conversion or exercise price data for applicable common stock equivalents included in these financial statements have been retroactively adjusted to reflect the reverse stock split.

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF MARCH 31, 2020 AND DECEMBER 31, 2019

	March 31, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets		
Cash	$ 6,835	$ 6,835
Total current assets	6,835	6,835
Acquired patents, net	18,935	19,836
Total assets	$ 25,770	$ 26,671
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable & accrued interest	$ 748,613	$ 730,309
Unreimbursed Expenses	63,119	11,626
Advance from related party/shareholder	635,154	635,154
Total current liabilities	1,446,886	1,377,089
Total liabilities	1,446,886	1,377,089
Stockholders' deficit		
Common stock, $0.001 par value; 100,000,000 shares authorized; 8,535,619 and 8,458,048 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	8,536	8,458
Preferred stock, $0.001 par value; 6,795,000 shares authorized;		
Series A preferred stock: 1,520,937 issued and outstanding as of March 31, 2020 and December 31, 2019	1,521	1,521
Series B preferred stock: 129,267 issued and outstanding as of March 31, 2020 and December 31, 2019	129	129
Series C preferred stock: 66,575 issued and outstanding as of March 31, 2020 and December 31, 2019	67	67
Series D preferred stock: 263,586 issued and outstanding as of March 31, 2020 and December 31, 2019	264	264
Additional paid-in capital	26,026,999	25,853,134
Accumulated deficit	(27,458,632)	(27,213,991)
Total stockholders' deficit	(1,421,116)	(1,350,418)
Total liabilities and stockholders' deficit	$ 25,770	$ 26,671

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019 (UNAUDITED)

	Three Months Ended March 31,	
	2020	**2019**
Revenue	$ —	$ —
Operating expenses		
Research and development	149,891	126,358
General and administrative	94,750	22,373
Total operating expenses	244,641	148,731
Loss from operations	(244,641)	(148,731)
Net loss	$ (244,641)	$ (148,731)
Per share information:		
Net loss per common share, basic and diluted	$ (0.03)	$ (0.73)
Weighted average common shares outstanding, basic and diluted	8,496,834	202,996

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019 (UNAUDITED)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Amount	Shares	Par Amount			
Balances, December 31, 2018	202,996	$ 203	1,980,365	$ 1,981	$ 13,666,446	$ (23,788,684)	$ (10,120,054)
Net loss						(148,731)	(148,731)
Balances, March 31, 2019	202,996	$ 203	1,980,365	$ 1,981	$ 13,666,446	$ (23,937,415)	$ (10,268,785)
Balances, December 31, 2019	8,458,048	$ 8,458	1,980,365	$ 1,981	$ 25,853,134	$ (27,213,991)	$ (1,350,418)
Stock-based compensation	77,571	78	—	—	173,865	—	173,943
Net loss						(244,641)	(244,641)
Balances, March 31, 2020	8,535,619	$ 8,536	1,980,365	$ 1,981	$ 26,026,999	$ (27,458,632)	$ (1,421,116)

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019 (UNAUDITED)

	Three Months Ended March 31,	
	2020	**2019**
Operating activities:		
Net loss	$ (244,641)	$ (148,731)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	902	902
Stock-based compensation	173,943	—
Changes in operating assets and liabilities:		
Accounts payable	—	115,291
Accrued interest	18,303	10,165
Unreimbursed expenses (accrued)	51,493	(57,627)
Net cash used in operating activities	—	(80,000)
Net increase (decrease) in cash	—	(80,000)
Cash, beginning of period	6,835	85,102
Cash, end of period	$ 6,835	$ 5,102

See accompanied notes to unaudited financial statements.

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. Going Concern

The Company has prepared its financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

As of March 31, 2020, the Company had cash of $6,835. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional capital.

3. 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, 2019 and 2018 as reported in this Form S-1 have been omitted.

Basic and Diluted Loss per Share

As of March 31, 2020, the Company does not have common stock equivalents related to options or warrants. As of March 31, 2019, the Company had common stock equivalents related to warrants outstanding to acquire 2,675,602 shares of the Company's common stock.

As of March 31, 2020 and 2019, the Company has common stock equivalents related to 1,520,937shares of the Company's common stock issuable upon conversion of the Company's Series A Preferred Stock, 129,267 shares of the Company's common stock issuable upon conversion of the Company's Series B Preferred Stock, 66,575 shares of the Company's common stock issuable upon conversion of the Company's Series C Preferred Stock, and 263,586 shares of the Company's common stock issuable upon conversion of the Company's Series D Preferred Stock.

3. Significant Accounting Policies (cont.)

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

	Three Months Ended March 31,	
	2020	**2019**
Basic and diluted net loss per share calculation:		
Net loss, basic	(244,641)	(148,731)
Change in fair value of warrants	—	—
Net loss, diluted	(244,641)	(148,731)
Weighted average common shares outstanding, basic and diluted	8,496,834	202,996
Net loss per common share, basic and diluted	$ (0.03)	$ (0.73)

4. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total $63,119 as of March 31, 2020 and $11,626 as of December 31, 2019.

5. Commitments and Contingencies

License Obligation 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. 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 patent and license obligations to HJF, including accrued interest, plus accrued expenses for manufacturing of GP2 for the upcoming Phase III clinical trial through purchase orders with Polypeptide Laboratories and Stratum Medical, which total $748,613 as of March 31, 2020 and $730,309 as of December 31, 2019.

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.

6. Stockholders' Deficit

On September 30, 2019, the board of directors (the "Board") and stockholders of the Company adopted the Greenwich LifeSciences, Inc. 2019 Equity Incentive Plan setting aside and reserving 1,498,128 shares of common stock without any issuance of common stock or options under the plan. In addition, on September 30, 2019, the Board authorized the Company to enter into a lock-up/leak-out agreement with its shareholders, the size of the Board was increased from three to five members, two new members were appointed to the Board, $12 million of related party payables and 2,675,602 warrants were exchanged for 8,012,684 shares of the Company's common stock, and 155,433 shares of the Company's common stock were issued upfront at no value in consideration for services and 908,242 shares of the Company's common stock were authorized to be issued at $2,037,000 value based on various vesting schedules that start monthly vesting on October 1, 2019 and on the first day of each subsequent month.

As of March 31, 2020, 155,142 of the 908,242 shares of the common stock grant had vested at $347,886 value and 753,100 of these shares remain unvested and unrecognized at $1,689,114 value.

No new equity was raised in 2020 and 2019. The Company currently has Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, and Series D Preferred Stock issued and outstanding, with conversion prices ranging from $0.267 to $5.34 per share respectively with limited anti-dilution protection if a subsequent round is priced below a certain amount and with floors to limit the anti-dilution protection. The Series A Preferred Stock has liquidation preference over the Series B Preferred Stock, which has liquidation preference over the Series C Preferred, which has liquidation preference over the Series D Preferred Stock.

Warrants

As of March 31, 2020, there are no outstanding warrants to purchase shares of common stock, accounted for as equity or liabilities.

7. Subsequent Events

On June 22, 2020, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effectuate a 1-for-2.67 reverse stock split of the Company's issued and outstanding common and preferred stock. No fractional shares were issued and any fractional shares resulting from the stock split were rounded up to the nearest whole share. All common and preferred stock share and per-share data and conversion or exercise price data for applicable common stock equivalents included in these financial statements have been retroactively adjusted to reflect the reverse stock split.

1,000,000 Shares

Greenwich LifeSciences

Common Stock

Prospectus

, 2020

Aegis Capital Corp.

Until , 2020 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

PART II — INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All the amounts shown are estimates except the SEC registration fee and the FINRA filing fee.

		Amount to be paid
SEC registration fee	$	3,048
FINRA filing fee	$	4,025
The Nasdaq Capital Market initial listing fee	$	75,000
Transfer agent and registrar fees	$	10,000
Accounting fees and expenses	$	40,000
Legal fees and expenses	$	450,000
Printing and engraving expenses	$	20,000
Miscellaneous	$	5,002
Total	$	607,075

Item 14. Indemnification of Directors and Officers

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our Second Amended and Restated Certificate of Incorporation provides that no director of the Company shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon consummation of this offering, our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws will provide indemnification for our directors and officers to the fullest extent permitted by the DGCL. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our Second Amended and

Restated Certificate of Incorporation and Second Amended and Restated Bylaws will provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

As of the date of this prospectus, we have entered into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides, among other things, for indemnification to the fullest extent permitted by law and our Second Amended and Restated Certificate of Incorporation against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements provide for the advancement or payment of all expenses to the indemnitee and for the reimbursement to us if it is found that such indemnitee is not entitled to such indemnification.

In addition, upon consummation of this offering, we intend to obtain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Item 15. Recent Sales of Unregistered Securities

As of September 30, 2019, related party payables to the Company's officers and directors since January 1, 2010 totaled $12 million. As of September 30, 2019, the Company's officers, directors, and consultants owned outstanding warrants to acquire 2,675,602 shares of the Company's common stock. On September 30, 2019, the officers, directors, and consultants exchanged all related party payables and outstanding warrants for an aggregate of 8,012,684 shares of the Company's common stock, leaving the Company with no related party payables and no outstanding warrants as of September 30, 2019.

On September 30, 2019, the Company issued officers, directors, and consultants an aggregate of 155,433 shares of the Company's common stock as consideration for services.

From October 1, 2019 to December 31, 2019, the Company issued officers, directors and a consultant an aggregate of 77,571 shares of the Company's common stock for services rendered.

On December 30, 2019, the Company issued a consultant 9,364 shares of the Company's common stock for services rendered.

From January 1, 2020 to June 1, 2020, the Company issued officers, directors and a consultant 155,142shares of the Company's common stock for services rendered.

The foregoing offers, sales and issuances were exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D thereunder or Section 3(a)(9) of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1**	Amended and Restated Certificate of Incorporation, currently in effect
3.2**	Amendment to Amended and Restated Certificate of Incorporation dated March 2, 2018
3.3**	Amendment to Amended and Restated Certificate of Incorporation dated September 9, 2019
3.4*	Form of Second Amended and Restated Certificate of Incorporation, to be effective immediately prior to the closing of this offering
3.5**	Amended and Restated Bylaws, currently in effect
3.6*	Form of Second Amended and Restated Bylaws, to be effective immediately prior to the closing of this offering
3.7*	Amendment to Amended and Restated Certificate of Incorporation dated June 22, 2020
4.1*	Specimen Stock Certificate evidencing the shares of common stock
4.2*	Form of Underwriter Warrant
5.1*	Opinion of Sheppard, Mullin, Richter & Hampton LLP
10.1+**	2019 Equity Incentive Plan
10.2+**	Form of Indemnification Agreement with directors and executive officers
10.3*	Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company
10.4*	First Amendment to Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company
10.5*	Second Amendment to Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and the Company
10.6*	American Arbitration Association Award of Arbitrators
10.7+*	Form of Employment Agreement between the Company and Snehal Patel, to be effective on the closing of the offering contemplated by this registration statement
10.8*	Registration Rights Agreement
23.1*	Consent of MaloneBailey, LLP, independent registered public accounting firm
23.2*	Consent of Sheppard, Mullin, Richter & Hampton, LLP (included in Exhibit 5.1)
24.1**	Power of Attorney

_____

* Filed herewith.
** Previously filed.
\+ Indicates a management contract or any compensatory plan, contract or arrangement.

Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Greenwich LifeSciences, Inc. pursuant to the foregoing provisions, or otherwise, Greenwich LifeSciences, Inc .has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by Greenwich LifeSciences, Inc. of expenses incurred or paid by a director, officer or controlling person of Greenwich LifeSciences, Inc. in the successful

defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, Greenwich LifeSciences, Inc. will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned hereby further undertakes that:

(1) For purposes of determining any liability under the Securities Act the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by Greenwich LifeSciences, Inc. pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 1 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Stafford, State of Texas, on the 22nd day of June, 2020.

GREENWICH LIFESCIENCES, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated below.

Signature	Title	Date
/s/ Snehal Patel Snehal Patel	Chief Executive Officer and Director *(Principal Executive Officer and Principal Accounting and Financial Officer)*	June 22, 2020
* F. Joseph Daugherty	Chief Medical Officer and Director	June 22, 2020
* David McWilliams	Director	June 22, 2020
* Eric Rothe	Director	June 22, 2020
* Kenneth Hallock	Director	June 22, 2020

* By: /s/ Snehal Patel
Snehal Patel,
Attorney-In-Fact

ALTERNATE PAGES FOR SELLING STOCKHOLDER PROSPECTUS

The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated June 22, 2020

PROSPECTUS

Greenwich LifeSciences

1,685,394 Shares of Common Stock

The selling stockholders plan to sell an aggregate of up to 1,685,394 shares of common stock.

The selling stockholders must sell their shares at a fixed price per share of $8.00, which is the per share price of the shares being offered in our initial public offering, until such time as our shares are listed on a national securities exchange. Thereafter, the shares offered by this prospectus may be sold by the selling stockholders from time to time in the open market, through privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale or at negotiated prices. By separate prospectus (the "IPO Prospectus"), we have registered an aggregate of 1,000,000 shares of our common stock which we are offering for sale to the public through our underwriters, excluding any shares issuable upon the underwriters' over-allotment option.

We have applied to have our common stock listed on The Nasdaq Capital Market under the symbol "GLSI" which listing is a condition to this offering.

The distribution of the shares by the selling stockholders is not subject to any underwriting agreement. We will not receive any proceeds from the sale of the shares by the selling stockholders. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

We are an "emerging growth company" under the federal securities laws and have elected to be subject to reduced public company reporting requirements. An investment in our common stock may be considered speculative and involves a high degree of risk, including the risk of a substantial loss of your investment. See "Risk Factors" beginning on page 10 to read about the risks you should consider before buying shares of our common stock. An investment in our common stock is not suitable for all investors.

Sales of the shares of our common stock registered in this prospectus and the IPO Prospectus will result in two offerings taking place concurrently which might affect price, demand, and liquidity of our common stock.

You should rely only on the information contained in this prospectus and any prospectus supplement or amendment. We have not authorized anyone to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is only accurate on the date of this prospectus, regardless of the time of any sale of securities.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is , 2020

EXPLANATORY NOTE

Concurrent with this offering, the Company is registering shares of common stock in connection with an initial public offering of 1,000,000 shares of our common stock through the underwriters (excluding 150,000 shares which may be sold upon exercise of the underwriters' over-allotment option). Sales by stockholders that purchased shares in our common stock from the initial public offering may reduce the price of our common stock, demand for our shares and, as a result, the liquidity of your investment.

SELLING STOCKHOLDERS

This prospectus relates to the resale from time to time by the selling stockholders identified herein of up to an aggregate of 1,685,394 shares of our common stock (the "Resale Shares"). The selling stockholders have expressed an intent not to sell stock concurrently with the initial public offering.

The transactions by which the selling stockholders acquired their securities from us were exempt under the registration provisions of the Securities Act.

The Resale Shares referred to above are being registered to permit public sales of the Resale Shares, and the selling stockholders may offer the shares for resale from time to time pursuant to this prospectus. The selling stockholders may also sell, transfer or otherwise dispose of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares.

The table below sets forth certain information regarding the selling stockholders and the Resale Shares offered in this prospectus. The selling stockholders have had no material relationship with us within the past three years other than as described in the footnotes to the table below or as a result of their acquisition of our shares or other securities.

Beneficial ownership is determined in accordance with the rules of the SEC. The selling stockholder's percentage of ownership of our outstanding shares in the table below is based upon 10,593,555 shares of common stock issued and outstanding as of June 15, 2020 after giving effect to the conversion of all outstanding shares of preferred stock.

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before this Offering[1]	Percentage of Common Stock Beneficially Owned Before this Offering	Shares of Common Stock Offered in this Offering	Shares of Common Stock Beneficially Owned After this Offering[2]	Percentage of Common Stock Beneficially Owned After this Offering[2]
Yosajo MI Trust 1[3]	187,266	1.77%	187,266	0	0%
Yosajo MI Trust 2[3]	187,266	1.77%	187,266	0	0%
Yosajo MI Trust 3[3]	187,266	1.77%	187,266	0	0%
Yosajo MA Trust 1[3]	187,266	1.77%	187,266	0	0%
Yosajo MA Trust 2[3]	187,266	1.77%	187,266	0	0%
Yosajo MA Trust 3[3]	187,266	1.77%	187,266	0	0%
Brent Thomas Henderson 2010 Trust[4]	187,266	1.77%	187,266	0	0%
David Brian Henderson 2010 Trust[4]	187,266	1.77%	187,266	0	0%
Thatcher Duncan Hallock 2010 Trust[4]	187,266	1.77%	187,266	0	0%
TOTAL			**1,685,394**		

(1) Under applicable SEC rules, a person is deemed to beneficially own securities which the person has the right to acquire within 60 days through the exercise of any option or warrant or through the conversion of a convertible security. Also under applicable SEC rules, a person is deemed to be the "beneficial owner" of a security with regard to which the person directly or indirectly, has or shares (a) voting power, which includes the power to vote or direct the voting of the security, or (b) investment power, which includes the power to dispose, or direct the disposition, of the security, in each case, irrespective of the person's economic interest in the security. To our knowledge, subject to community property laws where applicable, each person named in the table has sole voting and investment power with respect to the shares of common stock shown as beneficially owned by such selling stockholder, except as otherwise indicated in the footnotes to the table.

(2) Represents the amount of shares that will be held by the selling stockholder after completion of this offering based on the assumptions that (a) all Resale Shares registered for sale by the registration statement of which this prospectus is part will be sold and (b) no other shares of our common stock are acquired or sold by the selling stockholder prior to completion of this offering. However, each selling stockholder may sell all, some or none of the Resale Shares offered pursuant to this prospectus and may sell other shares of our common stock that they may own pursuant to another registration statement under the Securities Act or sell some or all of their shares pursuant to an exemption from the registration provisions of the Securities Act, including under Rule 144.

(3) Pankaj Patel is the Trustee of the trust and in such capacity has the right to vote and dispose of the securities held by such trust.

(4) Jim Hallock is the Trustee of the trust and in such capacity has the right to vote and dispose of the securities held by such trust.

PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell any or all of their Resale Shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. If the Resale Shares are sold through underwriters, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The Resale Shares may be sold in one or more transactions at a price of $8.00 per share until our shares are listed on The Nasdaq Capital Market and thereafter at prevailing market prices or privately negotiated prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. In general, a person who has beneficially owned restricted shares of our common stock for at least six months, in the event we have been a reporting company under the Exchange Act for at least 90 days, would be entitled to sell such securities, provided that such person is not deemed to be an affiliate of ours at the time of sale or to have been an affiliate of ours at any time during the three months preceding the sale.

The selling stockholders may also engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the Resale Shares by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of the Resale Shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the Resale Shares if liabilities are imposed on that person under the Securities Act.

In connection with the sale of the Resale Shares, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of our common stock in the course of hedging in positions they assume. The selling stockholders may also sell Resale Shares short and deliver shares of our common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge the Resale Shares to broker-dealers that in turn may sell such shares.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the Resale Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Resale Shares from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the Resale Shares in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the Resale Shares from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgees, transferees or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the Resale Shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the Resale Shares may be deemed to be an "Underwriter" within the meaning of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, such broker-dealers or agents and any profit realized on the Resale Shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the Resale Shares is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of Resale Shares being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers. Under the securities laws of some states, the Resale Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the Resale Shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with. There can be no assurance that any selling stockholder will sell any or all of the Resale Shares registered pursuant to the registration statement, of which this prospectus forms a part.

Each selling stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Resale Shares. None of the selling stockholders who are affiliates of broker-dealers, other than the initial purchasers in private transactions, purchased the Resale Shares outside of the ordinary course of business or, at the time of the purchase of the Resale Shares, had any agreements, plans or understandings, directly or indirectly, with any person to distribute the securities.

We are required to pay all fees and expenses incident to the registration of the Resale Shares. Except as provided for indemnification of the selling stockholders, we are not obligated to pay any of the expenses of any attorney or other advisor engaged by a selling stockholder. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of the Resale Shares, we will file a post-effective amendment to the registration statement. If the selling stockholders use this prospectus for any sale of the Resale Shares, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of the Resale Shares and activities of the selling stockholders, which may limit the timing of purchases and sales of any of the Resale Shares by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the Resale Shares to engage in passive market-making activities with respect to the Resale Shares. Passive market making involves transactions in which a market maker acts as both our underwriter and as a purchaser of our common stock in the secondary market. All of the foregoing may affect the marketability of the Resale Shares and the ability of any person or entity to engage in market-making activities with respect to the Resale Shares.

Once sold under the registration statement, of which this prospectus forms a part, the Resale Shares will be freely tradable in the hands of persons other than our affiliates.

USE OF PROCEEDS

We will not receive proceeds from sales of the Resale Shares made under this prospectus.

DETERMINATION OF OFFERING PRICE

There currently is no public market for our common stock. The shares of common stock may be sold in one or more transactions at a price of $8.00 per share until our shares are listed on The Nasdaq Capital Market and thereafter at prevailing market prices or privately negotiated prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. See “Plan of Distribution” above for more information.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities being offered by this prospectus will be passed upon by Sheppard, Mullin, Richter & Hampton LLP, New York, New York.

Exhibit 1.1

GREENWICH LIFESCIENCES, INC.

UNDERWRITING AGREEMENT

_____ Shares of Common Stock

_____, 2020

Aegis Capital Corp.
810 Seventh Avenue, 18th Floor
New York, NY 10019
As Representative of the
Several Underwriters Named on Schedule I hereto

Ladies and Gentlemen:

GREENWICH LIFESCIENCES, INC., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell to the underwriters named in **Schedule I** hereto (the "Underwriters," or each, an "Underwriter"), for whom Aegis Capital Corp. is acting as representative (the "Representative"), an aggregate of _____ authorized but unissued shares of common stock, par value $0.001 per share, (the "Common Stock") of the Company (the "Firm Shares"). The Company also proposes to sell to the Underwriters, upon the terms and conditions set forth in Section 4 hereof, up to an additional _____ shares of Common Stock (the "Option Shares"). The Firm Shares and the Option Shares are hereinafter collectively referred to as the "Shares" or the "Securities".

The Company and the several Underwriters hereby confirm their agreement as follows:

1. Registration Statement and Prospectus.

The Company has prepared and filed with the Securities and Exchange Commission (the "Commission") a registration statement covering the Securities and Representative's Securities (as defined in Section 4(f) hereof) on Form S-1 (File No. 333-238829) under the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations (the "Rules and Regulations") of the Commission thereunder, including a preliminary prospectus relating to the Securities and such amendments to such registration statement (including post effective amendments) as may have been required to the date of this Agreement. Such registration statement, as amended (including any post effective amendments), has been declared effective by the Commission. Such registration statement, including amendments thereto (including post effective amendments thereto) and all documents and information deemed to be a part of the Registration Statement through incorporation by reference or otherwise at the time of effectiveness thereof (the "Effective Time"), the exhibits and any schedules thereto at the Effective Time or thereafter during the period of effectiveness and the documents and information otherwise deemed to be a part thereof or included therein by the Securities Act or otherwise pursuant to the Rules and Regulations at the Effective Time or thereafter during the period of effectiveness, is herein called the "Registration Statement." If the Company has filed or files an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the "Rule 462 Registration Statement"), then any reference herein to the term Registration Statement shall include such Rule 462 Registration Statement. Any preliminary prospectus included in the Registration Statement or filed with the Commission pursuant to Rule 424(a) under the Securities Act is hereinafter called a "Preliminary Prospectus." The Preliminary Prospectus relating to the Securities and Representative's Securities that was included in the Registration Statement immediately prior to the pricing of the offering contemplated hereby is hereinafter called the "Pricing Prospectus."

The Company is filing with the Commission pursuant to Rule 424 under the Securities Act a final prospectus covering the Securities, which includes the information permitted to be omitted therefrom at the Effective Time by Rule 430A under the Securities Act. Such final prospectus, as so filed, is hereinafter called the "Final Prospectus." The Final Prospectus, the Pricing Prospectus and any preliminary prospectus in the form in which they were included in the Registration Statement or filed with the Commission pursuant to Rule 424 under the Securities Act is hereinafter called a "Prospectus." Reference made herein to any Preliminary Prospectus, the Pricing Prospectus or to the Prospectus shall be deemed to refer to and include any documents incorporated by reference therein.

2. Representations and Warranties of the Company Regarding the Offering.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date (as defined in Section 4(d) below) and as of each Option Closing Date (as defined in Section 4(b) below), as follows:

(i) **No Material Misstatements or Omissions**. At each time of effectiveness, at the date hereof, at the Closing Date, and at each Option Closing Date, if any, the Registration Statement and any post-effective amendment thereto complied or will comply in all material respects with the requirements of the Securities Act and the Rules and Regulations and did not, does not, and will not, as the case may be, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Time of Sale Disclosure Package (as defined below) as of the date hereof and at the Closing Date and on each Option Closing Date, any roadshow or investor presentations delivered to and approved by the Underwriter for use in connection with the marketing of the offering of the Securities (the "Marketing Materials"), if any, and the Final Prospectus, as amended or supplemented, as of its date, at the time of filing pursuant to Rule 424(b) under the Securities Act, at the Closing Date, and at each Option Closing Date, if any, did not, does not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences shall not apply to statements in or omissions from the Registration Statement, the Time of Sale Disclosure Package or any Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f). The Registration Statement contains all exhibits and schedules required to be filed by the Securities Act or the Rules and Regulations. No order preventing or suspending the effectiveness or use of the Registration Statement or any Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission.

(ii) **Marketing Materials**. The Company has not distributed any prospectus or other offering material in connection with the offering and sale of the Securities other than the Time of Sale Disclosure Package and the roadshow or investor presentations delivered to and approved by the Representative for use in connection with the marketing of the offering of the Securities (the "Marketing Materials").

(iii) **Accurate Disclosure**. (A) The Company has provided a copy to the Underwriters of each Issuer Free Writing Prospectus (as defined below) used in the sale of Securities. The Company has filed all Issuer Free Writing Prospectuses required to be so filed with the Commission, and no order preventing or suspending the effectiveness or use of any Issuer Free Writing Prospectus is in effect and no proceedings for such purpose have been instituted or are pending, or, to the knowledge of the Company, are contemplated or threatened by the Commission. When taken together with the rest of the Time of Sale Disclosure Package or the Final Prospectus, no Issuer Free Writing Prospectus, as of its issue date and at all subsequent times though the completion of the public offer and sale of the Securities, has, does or will include (1) any untrue statement of a material fact or omission to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or (2) information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Final Prospectus. The representations and warranties set forth in the immediately preceding sentence shall not apply to statements in or omissions from the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company by any Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f). As used in this paragraph and elsewhere in this Agreement:

(1) "Time of Sale Disclosure Package" means the Prospectus most recently filed with the Commission before the time of this Agreement, including any preliminary prospectus supplement deemed to be a part thereof, each Issuer Free Writing Prospectus, and the description of the transaction provided by the Underwriters included on **Schedule II**.

(2) "Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 under the Securities Act, relating to the Securities that (A) is required to be filed with the Commission by the Company, or (B) is exempt from filing pursuant to Rule 433(d)(5)(i) or (d)(8) under the Securities Act, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act.

(B) At the time of filing of the Registration Statement and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 under the Securities Act or an "excluded issuer" as defined in Rule 164 under the Securities Act.

(C) Each Issuer Free Writing Prospectus listed on **Schedule III** satisfied, as of its issue date and at all subsequent times through the Prospectus Delivery Period (as defined in Section 5(a) hereof), all other conditions as may be applicable to its use as set forth in Rules 164 and 433 under the Securities Act, including any legend, record-keeping or other requirements.

(iv) **Financial Statements**. The financial statements of the Company, together with the related notes and schedules, included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Commission thereunder, and fairly present in all material respects the financial condition of the Company as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with U.S. generally accepted accounting principles ("GAAP") consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP). No other financial statements, pro forma financial information or schedules are required under the Securities Act, the Exchange Act, or the Rules and Regulations to be included in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus.

(v) **Pro Forma Financial Information**. The pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus include assumptions that provide a reasonable basis for presenting the significant effects directly attributable to the transactions and events described therein, the related pro forma adjustments give appropriate effect to those assumptions, and the pro forma adjustments reflect the proper application of those adjustments to the historical financial statements amounts in the pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. The pro forma financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus comply as to form in all material respects with the application requirements of Regulation S-X under the Exchange Act.

(vi) **Independent Accountants.** To the Company's knowledge, MaloneBailey, LLP, which has expressed its opinion with respect to the audited financial statements and schedules included as a part of the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, is an independent public accounting firm with respect to the Company within the meaning of the Securities Act and the Rules and Regulations.

(vii) **Accounting Controls.** The Company will maintain a system of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by, or under the supervision of, its principal executive and principal financial officer, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(viii) **Forward-Looking Statements**. The Company had a reasonable basis for, and made in good faith, each "forward-looking statement" (within the meaning of Section 27A of the Securities Act or Section 21E of the Exchange Act) contained or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package, the Final Prospectus or the Marketing Materials.

(ix) **Statistical and Marketing-Related Data**. All statistical or market-related data included or incorporated by reference in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, or included in the Marketing Materials, are based on or derived from sources that the Company reasonably believes to be reliable and accurate, and the Company has obtained the written consent to the use of such data from such sources, to the extent required.

(x) **Pursuant to the Exchange Act**. The Company has filed with the Commission a Form 8-A (File Number 001-_____) providing for the registration pursuant to Section 12(b) under the Exchange Act of the shares of Common Stock. The registration of the shares of Common Stock under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the shares of Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

(xi) **Stock Exchange Listing**. The shares of Common Stock have been approved for listing on The Nasdaq Capital Market ("Nasdaq"), and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from Nasdaq, nor has the Company received any written notification that Nasdaq is contemplating terminating such listing.

(xii) **Absence of Manipulation**. The Company has not taken, directly or indirectly, any action that is designed to or that has constituted or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xiii) **Investment Company Act**. The Company is not and, after giving effect to the offering and sale of the Securities and the application of the net proceeds thereof, will not be an "investment company," as such term is defined in the Investment Company Act of 1940, as amended.

(b) Any certificate signed by any officer of the Company and delivered to the Underwriters or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

3. Representations and Warranties Regarding the Company.

(a) The Company represents and warrants to, and agrees with, the several Underwriters, as of the date hereof and as of the Closing Date and as of each Option Closing Date, if any, as follows:

(i) **Good Standing**. The Company has been duly organized and is validly existing as a corporation or other entity in good standing under the laws of its jurisdiction of incorporation or organization. The Company has the power and authority (corporate or otherwise) to own its properties and conduct its business as currently being carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation or other entity in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary, except where the failure to so qualify would not have or be reasonably likely to result in a material adverse effect upon the business, prospects, properties, operations, condition (financial or otherwise) or results of operations of the Company, or in its ability to perform its obligations under this Agreement or the Representative's Warrant Agreement (as defined in Section 4(f)) ("Material Adverse Effect").

(ii) **Validity and Binding Effect of Agreements**. This Agreement and the Representative's Warrant Agreement have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(iii) **Contracts**. The execution, delivery and performance of this Agreement and the Representative's Warrant Agreement and the consummation of the transactions herein and therein contemplated will not (A) result in a breach or violation of any of the terms and provisions of, or constitute a default under, any law, order, rule or regulation to which the Company is subject, or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, breach or default is not reasonably likely to result in a Material Adverse Effect, (B) conflict with, result in any violation or breach of, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) (a "Default Acceleration Event") of, any agreement, lease, credit facility, debt, note, bond, mortgage, indenture or other instrument (the "Contracts") or obligation or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, except to the extent that such conflict, default, or Default Acceleration Event is not reasonably likely to result in a Material Adverse Effect, or (C) result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Company's Amended and Restated Certificate of Incorporation, as amended (" Certificate of Incorporation"), or Amended and Restated Bylaws ("Bylaws").

(iv) **No Violations of Governing Documents**. The Company is not in violation, breach or default under its Certificate of Incorporation, Bylaws or other equivalent organizational or governing documents.

(v) **Consents**. No consents, approvals, orders, authorizations or filings are required on the part of the Company in connection with the execution, delivery or performance of this Agreement and the Representative's Warrant Agreement and the issue and sale of the Securities and the Representative's Securities, except (A) the registration under the Securities Act of the Securities and Representative's Securities, which has been effected, (B) the necessary filings and approvals from Nasdaq to list the Securities and the shares of Common Stock underlying the Representative's Warrants, (C) such consents, approvals, authorizations, registrations or qualifications as may be required under state or foreign securities or Blue Sky laws and the rules of the Financial Industry Regulatory Authority, Inc. ("FINRA") in connection with the purchase and distribution of the Securities by the several Underwriters, (D) such consents and approvals as have been obtained and are in full force and effect, and (E) such consents, approvals, orders, authorizations and filings the failure of which to make or obtain is not reasonably likely to result in a Material Adverse Effect.

(vi) **Capitalization**. The Company has an authorized capitalization as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. All of the issued and outstanding shares of capital stock of the Company are duly authorized and validly issued, fully paid and nonassessable, and have been issued in compliance with all applicable securities laws, and conform to the description thereof in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. Since the respective dates as of which information is provided in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company has not entered into or granted any convertible or exchangeable securities, options, warrants, agreements, contracts or other rights in existence to purchase or acquire from the Company any shares of the capital stock of the Company. The Shares and Representative's Securities have been duly authorized for issuance and sale and, when issued and paid for, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Shares and Representative's Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Shares and Representative's Securities has been duly and validly taken. The Shares and Representative's Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. All corporate action required to be taken for the authorization, issuance and sale of the Representative's Warrant Agreement has been duly and validly taken; the shares of Common Stock issuable upon exercise of the Representative's Warrant (as defined in Section 4(f) hereof) have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when paid for and issued in accordance with the Representative's Warrant and the Representative's Warrant Agreement, such shares of Common Stock will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; and such shares of Common Stock are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company

(vii) **Taxes**. The Company has (a) filed all foreign, federal, state and local tax returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof (except where the failure to file would not, individually or in the aggregate, have a Material Adverse Effect) and (b) paid all taxes (as hereinafter defined) shown as due and payable on such returns that were filed and has paid all taxes imposed on or assessed against the Company (except where the failure to pay would not, individually or in the aggregate, have a Material Adverse Effect). The provisions for taxes payable, if any, shown on the financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. To the knowledge of the Company, no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company, and no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(viii) **Material Change**. Since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, and except as disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, (a) the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock; (c) there has not been any change in the capital stock of the Company (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants, upon the conversion of outstanding shares of preferred stock or other convertible securities, due to the vesting of outstanding stock grants or the issuance of restricted stock awards or restricted stock units under the Company's existing stock awards plan, or any new grants thereof in the ordinary course of business), (d) there has not been any material change in the Company's long-term or short-term debt, other than periodic accruals in the ordinary course pursuant to the terms of the Company's outstanding debt, and (e) there has not been the occurrence of any Material Adverse Effect.

(ix) **Absence of Proceedings**. There is no action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which has not been disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(x) **Regulatory**. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus: (i) the Company has not received notice from any Governmental Entity (as defined below) alleging or asserting noncompliance with any Applicable Regulations (as defined below) or Authorizations (as defined below); (ii) the Company is and has been in material compliance with federal, state or foreign statutes, laws, ordinances, rules and regulations applicable to the Company (collectively, "Applicable Regulations"); (iii) the Company possesses all licenses, certificates, approvals, clearances, consents, authorizations, qualifications, registrations, permits, and supplements or amendments thereto required by any such Applicable Regulations and/or to carry on its businesses as now conducted ("Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iv) the Company has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Regulations or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, has there been any material noncompliance with or violation of any Applicable Regulations by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by any Governmental Entity; and (v) the Company has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action. Neither the Company nor, to the Company's knowledge, any of its directors, officers, employees or agents has been convicted of any crime under any Applicable Regulations. "Governmental Entity" shall be defined as any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency (whether foreign or domestic) having jurisdiction over the Company or any of its properties, assets or operations.

(xi) **Good Title**. The Company has good and marketable title to all property (whether real or personal) described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as being owned by it that are material to the business of the Company, in each case free and clear of all liens, claims, security interests, other encumbrances or defects, except those that are disclosed in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus and those that are not reasonably likely to result in a Material Adverse Effect. The property held under lease by the Company is held by it under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company.

(xii) **Intellectual Property**. The Company owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights ("Intellectual Property Rights") necessary for the conduct of the business of the Company as currently carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus. To the knowledge of the Company, no action or use by the Company necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Final Prospectus will involve or give rise to any infringement of, or license or similar fees for, any Intellectual Property Rights of others. The Company has not received any notice alleging any such infringement, fee or conflict with asserted Intellectual Property Rights of others. Except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Effect (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), reasonably be expected to result in a Material Adverse Effect; (C) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii) reasonably be expected to result in a Material Adverse Effect; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 3(a)(xii), reasonably be expected to result in a Material Adverse Effect; and (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company, or actions undertaken by the employee while employed with the Company and could reasonably be expected to result, individually or in the aggregate, in a Material Adverse Effect. To the Company's knowledge, all material technical information developed by and belonging to the Company which has not been patented has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus and are not described therein. The Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons. To the Company's knowledge, there is no prior art or public or commercial activity that may render any patent included in the Intellectual Property Rights invalid or that would preclude the issuance of any patent on any patent application included in the Intellectual Property which has not been disclosed to the U.S. Patent and Trademark Office or the relevant foreign patent authority, as the case may be. The Company has not, and to the Company's knowledge, no third party has, committed any act or omitted to undertake any act the effect of such commission or omission would reasonably be expected to result in a legal determination that any item of Intellectual Property Rights thereby was rendered invalid or unenforceable in whole or in part. The manufacture, use and sale of the products or product candidates described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus as under development by the Company fall within the scope of one or more claims of the patents or patent applications included in the Intellectual Property Rights. Other than information disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property Rights that are owned or purported to be owned by the Company that would confer upon any governmental agency or body, university, college, other educational institution or research center any claim or right in or to any such Intellectual Property Rights.

(xiii) **Employment Matters**. There is (A) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relation board or any foreign labor relations board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (B) no labor disturbance by the employees of the Company exists or, to the Company's knowledge, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that could reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

(xiv) **ERISA Compliance**. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would reasonably be expected to, singularly or in the aggregate, have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and could not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and, to the Company's knowledge, nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, cause the loss of such qualification.

(xv) **Environmental Matters**. The Company is in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses ("Environmental Laws"), except where the failure to comply has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability, except for any violation or liability which has not had and would not reasonably be expected to have, singularly or in the aggregate, a Material Adverse Effect; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company has knowledge.

(xvi) **SOX Compliance**. The Company has taken all actions it deems reasonably necessary or advisable to take on or prior to the date of this Agreement to assure that, upon and at all times after the Effective Date, it will be in compliance in all material respects with all applicable provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof. (the "Sarbanes-Oxley Act") that are then in effect and will take all action it deems reasonably necessary or advisable to assure that it will be in compliance in all material respects with other applicable provisions of the Sarbanes-Oxley Act not currently in effect upon it and at all times after the effectiveness of such provisions.

(xvii) **Money Laundering Laws**. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xviii) **Foreign Corrupt Practices Act**. Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent, affiliate of the Company or any other person acting on behalf of the Company, is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xix) **OFAC**. Neither the Company nor, to the knowledge of the Company, any director, officer, employee, representative, agent or affiliate of the Company or any other person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering of the Securities contemplated hereby, or lend, contribute or otherwise make available such proceeds to any person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(xx) **Insurance**. Following the consummation of the offering contemplated hereby , the Company will carry insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries.

(xxi) **Books and Records**. The minute books of the Company have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a complete summary of all meetings and actions of the board of directors (including each board committee) and stockholders of the Company (or analogous governing bodies and interest holders, as applicable), since the time of its incorporation or organization through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all transactions referred to in such minutes.

(xxii) **No Violation**. Neither the Company nor, to its knowledge, any other party is in violation, breach or default of any Contract that has resulted in or could reasonably be expected to result in a Material Adverse Effect.

(xxiii) **Continued Business**. No supplier, customer, distributor or sales agent of the Company has notified the Company that it intends to discontinue or decrease the rate of business done with the Company, except where such discontinuation or decrease has not resulted in and could not reasonably be expected to result in a Material Adverse Effect.

(xxiv) **No Finder's Fee**. There are no claims, payments, issuances, arrangements or understandings for services in the nature of a finder's, consulting or origination fee with respect to the introduction of the Company to any Underwriter or the sale of the Securities hereunder or any other arrangements, agreements, understandings, payments or issuances with respect to the Company that may affect the Underwriters' compensation, as determined by FINRA.

(xxv) **No Fees.** Except as disclosed to the Representative in writing, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to (i) any person, as a finder's fee, investing fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who provided capital to the Company, (ii) any FINRA member, or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member within the twelve (12) month period prior to the date on which the Registration Statement was filed with the Commission ("Filing Date") or thereafter.

(xxvi) **Proceeds**. None of the net proceeds of the offering will be paid by the Company to any participating FINRA member or any affiliate or associate of any participating FINRA member, except as specifically authorized herein.

(xxvii) **No FINRA Affiliations**. To the Company's knowledge and except as disclosed to the Representative in writing, no (i) officer or director of the Company or (ii) owner of 5% or more of any class of the Company's securities or (iii) owner of any amount of the Company's unregistered securities acquired within the 180-day period prior to the Filing Date, has any direct or indirect affiliation or association with any FINRA member. The Company will advise the Representative and counsel to the Underwriters if it becomes aware that any officer, director of the Company or any owner of 5% or more of any class of the Company's securities is or becomes an affiliate or associated person of a FINRA member participating in the offering.

(xxviii) **No Financial Advisor**. Other than the Underwriters, no person has the right to act as an underwriter or as a financial advisor to the Company in connection with the transactions contemplated hereby.

(xxix) **Data Privacy and Security Laws**. The Company is, and at all prior times was, in material compliance with all applicable state and federal data privacy and security laws and regulations in the United States, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act, and all applicable provincial and federal data privacy and security laws and regulations in Canada, including without limitation the Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5) ("PIPEDA"); and the Company has taken commercially reasonable actions to prepare to comply with, and have been and currently are in compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). To ensure compliance with the Privacy Laws, the Company has in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) Protected Health Information as defined by HIPAA; (iv) "personal information", "personal health information". and "business contact information" as defined by PIPEDA; (v) "personal data" as defined by GDPR; and (vi) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. The Company has at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies: (i) it has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(xxx) **No Registration Rights**. Except as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights which have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.

(xxxi) **Prior Sales of Securities**. Except as set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, stock option plans or other employee compensation plans, pursuant to outstanding preferred stock, options, rights or warrants or other outstanding convertible securities or in connection with the vesting of any outstanding stock grants.

(xxxii) **Compliance with Laws.** The Company: (A) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the Company, including, without limitation, all statutes, rules, or regulations relating to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company and, without limiting the foregoing, include (i) the Federal Food, Drug, and Cosmetic Act (the "FDCA"), (ii) the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and Laws applicable to hazardous or regulated substances and radioactive or biologic materials, (iii) the federal Anti-Kickback Statute, (iv) the False Claims Act, (v) the Civil Monetary Penalties Law, (vi) the Physician Payments Sunshine Act, (vii) the criminal False Claims Law, (viii) the HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act and (ix) licensing and certification laws covering any aspect of the business of the Company ("Applicable Laws"), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; (B) has not received any warning letter, untitled letter or other correspondence or notice from any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its business as now conducted ("Applicable Authorizations"); (C) possesses all material Application Authorizations and such Applicable Authorizations are valid and in full force and effect and are not in material violation of any term of any such Applicable Authorizations; (D) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product operation or activity is in violation of any Applicable Laws or Applicable Authorizations and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding nor, to the Company's knowledge, has there been any material noncompliance with or violation of any Applicable Laws by the Company that could reasonably be expected to require the issuance of any such communication or result in an investigation, corrective action, or enforcement action by any Governmental Entity; (E) has not received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Applicable Authorizations and has no knowledge that any such Governmental Entity has threatened or is considering such action; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Applicable Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(xxxiii) **FDA**. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company (each such product, a "FDA Product"), such FDA Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have or reasonably be expected to result in a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company, and the Company has not received any notice, warning letter or other communication from the FDA or any other Governmental Entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any FDA Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any FDA Product, (iii) imposes a clinical hold on any clinical investigation by the Company, (iv) enjoins production at any facility of the Company, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company, and which, either individually or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(xxxiv) **Clinical and Preclinical Studies**. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all authorizations and applicable laws and the rules and regulations promulgated thereunder and any applicable rules, regulations and policies of the jurisdiction in which such trials and studies are being conducted; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus are, to the Company's knowledge, accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company has not received any notices or correspondence from the FDA or any governmental entity requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

(xxxv) **Reverse Split**. The Company has taken all necessary corporate action to effectuate a reverse split of its issued and outstanding Common Stock and preferred stock on the basis of one (1) such share for each 2.67 shares of issued and outstanding Common Stock and Preferred Stock, as applicable (the "Reverse Split"), and such Reverse Split became effective on June 22, 2020.

4. Purchase, Sale and Delivery of Shares.

(a) On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell the Firm Shares to the several Underwriters, and the several Underwriters agree, severally and not jointly, to purchase the Firm Shares set forth opposite the names of the Underwriters in Schedule I hereto. The purchase price for each Firm Share shall be $_____ per share.

(b) The Company hereby grants to the Underwriters the option to purchase some or all of the Option Shares and, upon the basis of the warranties and representations and subject to the terms and conditions herein set forth, the Underwriter shall have the right, severally and not jointly, to purchase all or any portion of the Option Shares as may be necessary to cover over-allotments made in connection with the transactions contemplated hereby. The purchase price to be paid by the Underwriters for the Option Shares shall be $_____ per share. This option may be exercised by the Underwriters at any time and from time to time on or before the forty-fifth (45^{th}) day following the date hereof, by written notice to the Company (the "Option Notice"). The Option Notice shall set forth the aggregate number of Option Shares as to which the option is being exercised, and the date and time when the Option Shares are to be delivered (such date and time being herein referred to as the "Option Closing Date"); *provided*, *however*, that the Option Closing Date shall not be earlier than the Closing Date (as defined below) nor earlier than the first business day after the date on which the option shall have been exercised nor later than the fifth business day after the date on which the option shall have been exercised unless the Company and the Representative otherwise agree. If the Underwriters elect to purchase less than all of the Option Shares, the Company agrees to sell to the Underwriters the number of Option Shares obtained by multiplying the number of Option Shares specified in such notice by a fraction, the numerator of which is the number of Option Shares, as applicable, set forth opposite the name of the Underwriter in **Schedule I** hereto under the caption "Number of Option Shares to be Purchased" and the denominator of which is the total number of Option Shares.

(c) Payment of the purchase price for and delivery of the Option Shares shall be made on an Option Closing Date in the same manner and at the same office as the payment for the Firm Shares as set forth in subparagraph (d) below.

(d) The Firm Shares will be delivered by the Company to the Representative, for the respective accounts of the several Underwriters against payment of the purchase price therefor by wire transfer of same day funds payable to the order of the Company at the offices of Aegis Capital Corp., 810 Seventh Avenue, 18^{th} Floor, New York, NY 10019, or such other location as may be mutually acceptable, at 9:00 a.m. Eastern Time, on the second (or if the Firm Shares are priced, as contemplated by Rule 15c6-1(c) under the Exchange Act, after 4:30 p.m. Eastern time, the third) full business day following the date hereof, or at such other time and date as the Representative and the Company determine pursuant to Rule 15c6-1(a) under the Exchange Act, or, in the case of the Option Shares, at such date and time set forth in the Option Notice. The time and date of delivery of the Firm Shares is referred to herein as the "Closing Date." On the Closing Date, the Company shall deliver the Firm Shares which shall be registered in the name or names and shall be in such denominations as the Representative may request on behalf of the Underwriters at least one (1) business day before the Closing Date, to the respective accounts of the several Underwriters, which delivery shall with respect to the Firm Shares, be made through the facilities of the Depository Trust Company's Deposit or Withdrawal at Custodian ("DWAC") system.

(e) It is understood that the Representative has been authorized, for its own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Option Shares the Underwriters have agreed to purchase. The Representative, individually and not as the Representative of the Underwriters, may (but shall not be obligated to) make payment for any Securities to be purchased by any Underwriter whose funds shall not have been received by the Representative by the Closing Date or any Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) The Company hereby agrees to issue to the Representative (and/or its designees) on the Closing Date a five-year warrant (the "Representative's Warrant") for the purchase of an aggregate of ___ shares of Common Stock, representing up to 8% of the Firm Shares. The Representative's Warrant agreement, in the form attached hereto as Exhibit A (the "Representative's Warrant Agreement "), shall be exercisable, in whole or in part, commencing on a date which is six (6) months after the effective date (the "Effective Date") of the Registration Statement and expiring on the five-year anniversary of the Effective Date at an initial exercise price per share of Common Stock equal to 125% of the initial public offering price of the Firm Shares (subject to adjustment as set forth therein). The Representative's Warrant Agreement and the shares of Common Stock issuable upon exercise thereof are hereinafter referred to together as the "Representative's Securities." The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant Agreement and the underlying shares of Common Stock during the one hundred eighty (180) days after the Effective Date and by its acceptance thereof shall agree that it will not sell, transfer, assign, pledge or hypothecate the Representative's Warrant Agreement, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of one hundred eighty (180) days following the Effective Date to anyone other than (i) an Underwriter or a selected dealer in connection with the offering of the Securities or (ii) a bona fide officer or partner of the Representative or of any such Underwriter or selected dealer; and only if any such transferee agrees to the foregoing lock-up restrictions. Delivery of the Representative's Warrant Agreement shall be made on the Closing Date and shall be issued in the name or names and in such authorized denominations as the Representative may request.

5. Covenants.

(a) The Company covenants and agrees with the Underwriters as follows:

(i) The Company shall prepare the Final Prospectus in a form approved by the Representative and file such Final Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules and Regulations.

(ii) During the period beginning on the date hereof and ending on the later of the Closing Date or such date as determined by the Representative the Final Prospectus is no longer required by law to be delivered in connection with sales by an underwriter or dealer (the "Prospectus Delivery Period"), prior to amending or supplementing the Registration Statement, including any Rule 462 Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, the Company shall furnish to the Representative for review and comment a copy of each such proposed amendment or supplement, and the Company shall not file any such proposed amendment or supplement to which the Representative reasonably objects.

(iii) From the date of this Agreement until the end of the Prospectus Delivery Period, the Company shall promptly advise the Representative in writing (A) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (B) of the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, (C) of the time and date that any post-effective amendment to the Registration Statement becomes effective and (D) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending its use or the use of the Time of Sale Disclosure Package, the Final Prospectus or any Issuer Free Writing Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Stock from any securities exchange upon which it is listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time during the Prospectus Delivery Period, the Company will use its reasonable efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with the provisions of Rules 424(b), 430A, 430B or 430C as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission (without reliance on Rule 424(b)(8) or 164(b) of the Securities Act).

(iv) (A) During the Prospectus Delivery Period, the Company will comply with all requirements imposed upon it by the Securities Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, and by the Exchange Act, as now and hereafter amended, so far as necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the Time of Sale Disclosure Package, the Registration Statement and the Final Prospectus. If during the Prospectus Delivery Period any event occurs the result of which would cause the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary or appropriate in the opinion of the Company or its counsel or the Representative or counsel to the Underwriters to amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) to comply with the Securities Act, the Company will promptly notify the Representative, allow the Representative the opportunity to provide reasonable comments on such amendment, prospectus supplement or document, and will amend the Registration Statement or supplement the Final Prospectus (or if the Final Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) or file such document (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(B) If at any time during the Prospectus Delivery Period there occurred or occurs an event or development the result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement or any Prospectus or included or would include, when taken together with the Time of Sale Disclosure Package, an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(v) The Company shall take or cause to be taken all necessary action to qualify the Securities and Representative's Securities for sale under the securities laws of such jurisdictions as the Representative reasonably designates and to continue such qualifications in effect so long as required, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified, to execute a general consent to service of process in any state or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise subject.

(vi) The Company will furnish to the Underwriters and counsel to the Underwriters copies of the Registration Statement, each Prospectus, any Issuer Free Writing Prospectus, and all amendments and supplements to such documents, in each case as soon as available and in such quantities as the Underwriters may from time to time reasonably request.

(vii) The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement (which need not be audited) covering a 12-month period that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 of the Rules and Regulations.

(viii) The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid all expenses relating to the Offering, including, without limitation, (A) all filing fees and expenses relating to the registration of the Securities with the Commission, (B) all FINRA public offering filing fees, (C) all fees and expenses relating to the listing of the Common Stock on Nasdaq, (D) all fees, expenses, and disbursements relating to the registration or qualification of the Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of the Company's "blue sky" counsel, which will be Aegis' counsel) unless such filings are not required in connection with the Company's proposed Nasdaq listing, (E) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Securities under the securities law of such foreign jurisdiction as the Representative may reasonably designate, (F) the costs of all mailing and printing of the offering documents, (G) transfer and/or stamp taxes, if any, payable upon the transfer of Securities from the Company to the Representative, (H) the fees and expenses of the Company's counsel and accountants, and (I) a maximum of $100,000 for fees and expenses including "road show," diligence, and reasonable legal fees and disbursements for the Representative's counsel. If this Agreement is terminated, the Company will reimburse the Representative for reasonable fees and disbursements of counsel up to an aggregate of $50,000, incurred by the Underwriters in connection with their investigation, preparing to market and marketing the Shares or in contemplation of performing its obligations hereunder.

(ix) The Company intends to apply the net proceeds from the sale of the Securities to be sold by it hereunder for the purposes set forth in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus under the heading "Use of Proceeds".

(x) The Company has not taken and will not take, directly or indirectly, during the Prospectus Delivery Period, any action designed to or which might reasonably be expected to cause or result in, or that has constituted, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(xi) The Company represents and agrees that, unless it obtains the prior written consent of the Representative, and each Underwriter, severally, and not jointly, represents and agrees that, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the free writing prospectuses included in **Schedule III**. Any such free writing prospectus consented to by the Company and the Representative is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied or will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record-keeping.

(xii) The Company hereby agrees that, without the prior written consent of the Representative, it and any successors will not, during the period ending one hundred and eighty 180 days after the date hereof ("Lock-Up Period"), (a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock or the Company, (b) file or caused to be filed any registration statement with the Commission relating to the offering of any shares of capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock or (c) enter into any swap or other arrangement that transfers to another in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (a), (b) or (c) above is to be settled by delivery of shares of capital stock of the Company or any successors or such other securities, in cash or otherwise. The restrictions contained in the preceding sentence shall not apply to (i) the shares of Common Stock to be sold hereunder, (ii) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, the terms of which option, warrant or other outstanding convertible security are not thereafter amended, (iii) the issuance by the Company of shares of Common Stock upon the vesting of outstanding stock grants and (iv) the issuance by the Company of shares of Common Stock and Common Stock equivalents pursuant to equity incentive plans as described in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus.

(xiii) To engage and maintain, at its expense, a registrar and transfer agent for the Common Stock (if other than the Company).

(xiv) To use its reasonable best efforts to maintain the listing of the Common Stock on Nasdaq.

(xv) To not take, directly or indirectly, any action designed to cause or result in, or that has constituted or might reasonably be expected to constitute, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Securities.

(xvi) The Company further agrees that, in addition to the expenses payable pursuant to Section 5(a)(viii), on the Closing Date it shall pay to the Representative, by deduction from the net proceeds of the Offering contemplated herein, a non-accountable expense allowance equal to one percent (1%) of the gross proceeds received by the Company from the sale of the Shares; provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriters pursuant to Section 7 hereof. Notwithstanding the foregoing, any advance previously paid by the Company to the Representative against the Representative's non-accountable expense allowance actually anticipated to be incurred, which the Company and the Representative acknowledge is in the amount of $50,000 (the "Advance"), shall be applied towards the non-accountable expense allowance set forth herein; provided that the Representative will reimburse the Company for any remaining portion of the Advance to the extent amount of the Advance was not used for non-accountable expenses actually incurred by the Representative in the offering.

(xvii) The Representative shall have, for a period of nine (9) months after the Closing Date, a right of first refusal (the "Right of First Refusal") to act as sole book-running manager for any and all future public equity offerings of the Company or any subsidiary of the Company during such nine (9) month period, and the Company and the Representative will use commercially reasonable efforts to include at least one (1) additional investment bank in such offerings, mutually agreeable to both parties, that is focused on long-term holding institutional investors or other high quality retail investors during such period (the "Subject Transaction").

The Company shall notify the Representative of its intention to pursue a Subject Transaction, including the material terms thereof, by providing written notice thereof by email, registered mail or overnight courier service addressed to the Representative. If the Representative fails to exercise the Right of First Refusal with respect to any Subject Transaction within five (5) business days after the mailing of such written notice, then the Representative shall have no further claim or right with respect to the Subject Transaction. The Representative may elect, in its sole and absolute discretion, not to exercise its Right of First Refusal with respect to any Subject Transaction; provided that any such election by the Representative shall not adversely affect the Representative's Right of First Refusal with respect to any other Subject Transaction during the nine (9) month period agreed to above. If the Representative does not elect to exercise the Right of First Refusal and the material terms of the Subject Transaction are subsequently materially modified as to scope and nature, then the Company shall resubmit the proposed modified terms of the Subject Transaction in writing to the Representative, and the Representative shall have five (5) business days after receipt of such written notice to advise the Company of its election to participate in the proposed transaction.

6. Conditions of the Underwriter's Obligations. The respective obligations of the several Underwriters hereunder to purchase the Shares are subject to the accuracy, as of the date hereof and at all times through the Closing Date, and on each Option Closing Date (as if made on the Closing Date or such Option Closing Date, as applicable), of and compliance with all representations, warranties and agreements of the Company contained herein, the performance by the Company of its obligations hereunder and the following additional conditions:

(a) If filing of the Final Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, is required under the Securities Act or the Rules and Regulations, the Company shall have filed the Final Prospectus (or such amendment or supplement) or such Issuer Free Writing Prospectus with the Commission in the manner and within the time period so required (without reliance on Rule 424(b)(8) or 164(b) under the Securities Act); the Registration Statement shall remain effective; no stop order suspending the effectiveness of the Registration Statement or any part thereof, any Rule 462 Registration Statement, or any amendment thereof, nor suspending or preventing the use of the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened by the Commission; any request of the Commission or the Representative for additional information (to be included in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, any Issuer Free Writing Prospectus or otherwise) shall have been complied with to the satisfaction of the Representative.

(b) The Common Stock shall be approved for listing on Nasdaq, and satisfactory evidence thereof shall have been provided to the Representative and its counsel.

(c) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(d) The Representative shall not have reasonably determined, and advised the Company, that the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment thereof or supplement thereto, or any Issuer Free Writing Prospectus, contains an untrue statement of fact which, in the reasonable opinion of the Representative, is material, or omits to state a fact which, in the reasonable opinion of the Representative, is material and is required to be stated therein or necessary to make the statements therein not misleading.

(e) Intentionally Omitted.

(f) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Representative on behalf of the Underwriter the opinion and negative assurance letters of Sheppard, Mullin, Richter & Hampton LLP, corporate counsel to the Company, dated the Closing Date or the Option Closing Date, as applicable, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representative.

(g) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Representative on behalf of the Underwriter the opinion and negative assurance letters of Sheppard, Mullin, Richter & Hampton LLP, intellectual property counsel to the Company, dated the Closing Date or the Option Closing Date, as applicable, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representative

(h) The Underwriters shall have received a letter of MaloneBailey, LLP, on the date hereof and on the Closing Date and on each Option Closing Date, addressed to the Underwriters, confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualifications of accountants under Rule 2-01 of Regulation S-X of the Commission, and confirming, as of the date of each such letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Registration Statement, the Time of Sale Disclosure Package and the Final Prospectus, as of a date not prior to the date hereof or more than five (5) days prior to the date of such letter), the conclusions and findings of said firm with respect to the financial information and other matters required by the Underwriters.

(j) On the Closing Date and on each Option Closing Date, there shall have been furnished to the Underwriters a certificate, dated the Closing Date and on each Option Closing Date and addressed to the Underwriters, signed by the chief executive officer and the chief financial officer of the Company, in their capacity as officers of the Company, to the effect that:

(i) The representations and warranties of the Company in this Agreement that are qualified by materiality or by reference to any Material Adverse Effect are true and correct in all respects, and all other representations and warranties of the Company in this Agreement are true and correct, in all material respects, as if made at and as of the Closing Date and on the Option Closing Date, and the Company has complied in all material respects with all the agreements and satisfied all the conditions on its part required to be performed or satisfied at or prior to the Closing Date or on the Option Closing Date, as applicable;

(ii) No stop order or other order (A) suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof, (B) suspending the qualification of the Securities for offering or sale, or (C) suspending or preventing the use of the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus, has been issued, and no proceeding for that purpose has been instituted or, to their knowledge, is contemplated by the Commission or any state or regulatory body; and

(iii) There has been no occurrence of any event resulting or reasonably likely to result in a Material Adverse Effect during the period from and after the date of this Agreement and prior to the Closing Date or on the Option Closing Date, as applicable.

(k) On or before the date hereof, the Representative shall have received duly executed lock-up agreement, substantially in the form of **Exhibit B** hereto (each a "Lock-Up Agreement"), by and between the Representative and each of the parties specified in **Schedule IV.**

(l) On the Closing Date, the Company shall have delivered to the Representative executed copies of the Representative's Warrant Agreement.

(m) The Company shall have furnished to the Representative and its counsel such additional documents, certificates and evidence as the Representative and its counsel may have reasonably requested.

If any condition specified in this Section 6 shall not have been fulfilled when and as required to be fulfilled, this Agreement may be terminated by the Representative by notice to the Company at any time at or prior to the Closing Date or on the Option Closing Date, as applicable, and such termination shall be without liability of any party to any other party, except that Section 5(a)(viii), Section 7 and Section 8 shall survive any such termination and remain in full force and effect.

7. Indemnification and Contribution.

(a) The Company agrees to indemnify, defend and hold harmless each Underwriter, its affiliates, directors and officers and employees, and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which such Underwriter or such person may become subject, under the Securities Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon (i) an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to Rules 430A and 430B of the Rules and Regulations, or arise out of or are based upon the omission from the Registration Statement, or alleged omission to state therein, a material fact required to be stated therein or necessary to make the statements therein not misleading (ii) an untrue statement or alleged untrue statement of a material fact contained in the Time of Sale Disclosure Package, any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act (Written Testing-the-Waters Communications), any Prospectus, the Final Prospectus, or any amendment or supplement thereto, any Issuer Free Writing Prospectus, or the Marketing Materials or in any other materials used in connection with the offering of the Securities, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, (iii) in whole or in part, any inaccuracy in the representations and warranties of the Company contained herein, or (iv) in whole or in part, any failure of the Company to perform its obligations hereunder or under law, and will reimburse each Underwriter for any legal or other expenses reasonably incurred by it in connection with evaluating, investigating or defending against such loss, claim, damage, liability or action; *provided, however*, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Time of Sale Disclosure Package, any Written Testing-the-Waters Communications, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus, in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f).

(b) Each Underwriter, severally and not jointly, will indemnify, defend and hold harmless the Company, its affiliates, directors, officers and employees, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus, or any amendment or supplement thereto or any Issuer Free Writing Prospectus in reliance upon and in conformity with written information furnished to the Company by such Underwriter specifically for use in the preparation thereof, which written information is described in Section 7(f), and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with evaluating, investigating, and defending against any such loss, claim, damage, liability or action. The obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount applicable to the Shares to be purchased by such Underwriter hereunder actually received by such Underwriter.

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof, but the failure to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure. In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof; *provided*, *however*, that if (i) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (ii) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party), or (iii) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, the indemnified party shall have the right to employ a single counsel to represent it in any claim in respect of which indemnity may be sought under subsection (a) or (b) of this Section 7, in which event the reasonable fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the indemnified party as incurred.

The indemnifying party under this Section 7 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is a party or could be named and indemnity was or would be sought hereunder by such indemnified party, unless such settlement, compromise or consent (a) includes an unconditional release of such indemnified party from all liability for claims that are the subject matter of such action, suit or proceeding and (b) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 7 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering and sale of the Shares or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discount received by the Underwriters, in each case as set forth in the table on the cover page of the Final Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relevant intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in the first sentence of this subsection (d). The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim that is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount of the of the underwriting discount applicable to the Shares to be purchased by such Underwriter hereunder actually received by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' respective obligations to contribute as provided in this Section 7 are several in proportion to their respective underwriting commitments and not joint.

(e) The obligations of the Company under this Section 7 shall be in addition to any liability that the Company may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act; and the obligations of each Underwriter under this Section 7 shall be in addition to any liability that each Underwriter may otherwise have and the benefits of such obligations shall extend, upon the same terms and conditions, to the Company and its officers, directors and each person who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act.

(f) For purposes of this Agreement, each Underwriter severally confirms, and the Company acknowledges, that there is no information concerning such Underwriter furnished in writing to the Company by such Underwriter specifically for preparation of or inclusion in the Registration Statement, the Time of Sale Disclosure Package, any Prospectus, the Final Prospectus or any Issuer Free Writing Prospectus, other than the statement set forth in the last paragraph on the cover page of the Prospectus, the marketing and legal names of each Underwriter, and the statements set forth in the "Underwriting" section of the Registration Statement, the Time of Sale Disclosure Package, and the Final Prospectus only insofar as such statements relate to the amount of selling concession and re-allowance, if any, or to over-allotment, stabilization and related activities that may be undertaken by such Underwriter.

8. Representations and Agreements to Survive Delivery. All representations, warranties, and agreements of the Company contained herein or in certificates delivered pursuant hereto, including, but not limited to, the agreements of the several Underwriters and the Company contained in Section 5(a)(viii) and Section 7 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of the several Underwriters or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Shares to and by the Underwriters hereunder.

9. Termination of this Agreement.

(a) The Representative shall have the right to terminate this Agreement by giving notice to the Company as hereinafter specified at any time at or prior to the Closing Date or any Option Closing Date (as to the Option Shares to be purchased on such Option Closing Date only), if in the discretion of the Representative, (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Representative, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares (ii) trading in the Company's Common Stock shall have been suspended by the Commission or Nasdaq or trading in securities generally on the Nasdaq Stock Market, the NYSE or the NYSE MKT shall have been suspended, (iii) minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on the Nasdaq Stock Market, the NYSE or NYSE American, by such exchange or by order of the Commission or any other governmental authority having jurisdiction, (iv) a banking moratorium shall have been declared by federal or state authorities, (v) there shall have occurred any attack on, outbreak or escalation of hostilities or act of terrorism involving the United States any declaration by the United States of a national emergency or war, any substantial change or development involving a prospective substantial change in United States or other international political, financial or economic conditions or any other calamity or crisis, or (vi) the Company suffers any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, or (vii) in the judgment of the Representative, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the Time of Sale Disclosure Package or the Final Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business. Any such termination shall be without liability of any party to any other party except that the provisions of Section 5(a)(viii) and Section 7 hereof shall at all times be effective and shall survive such termination.

(b) If the Representative elects to terminate this Agreement as provided in this Section 9, the Company and the other Underwriters shall be notified promptly by the Representative by telephone, confirmed by letter.

(c) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (y) subject to a maximum reimbursement of $50,000, the Company will reimburse the Representative only for all actual, accountable out-of-pocket expenses (including the reasonable fees and disbursements of Sichenzia Ross Ference LLP, its counsel) reasonably incurred by the Representative in connection with the proposed purchase and sale of the Shares or in contemplation of performing their obligations hereunder and (z) no Underwriter who shall have failed or refused to purchase the Shares agreed to be purchased by it under this Agreement, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company, or to the other Underwriters for damages occasioned by its failure or refusal.

10. Substitution of Underwriters. If any Underwriter or Underwriters shall default in its or their obligations to purchase Shares hereunder on the Closing Date or any Option Closing Date and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed to purchase does not exceed ten percent (10%) of the total number of Shares to be purchased by all Underwriters on such Closing Date or Option Closing Date, the other Underwriters shall be obligated severally, in proportion to their respective commitments hereunder, to purchase the Shares which such defaulting Underwriter or Underwriters agreed but failed to purchase on such Closing Date or Option Closing Date. If any Underwriter or Underwriters shall so default and the aggregate number of Shares with respect to which such default or defaults occur is more than ten percent (10%) of the total number of Shares to be purchased by all Underwriters on such Closing Date or Option Closing Date and arrangements satisfactory to the remaining Underwriters and the Company for the purchase of such Shares by other persons are not made within forty-eight (48) hours after such default, this Agreement shall terminate.

If the remaining Underwriters or substituted Underwriters are required hereby or agree to take up all or part of the Shares of a defaulting Underwriter or Underwriters on such Closing Date or Option Closing Date as provided in this Section 10, (i) the Company shall have the right to postpone such Closing Date or Option Closing Date for a period of not more than five (5) full business days in order to permit the Company to effect whatever changes in the Registration Statement, the Final Prospectus, or in any other documents or arrangements, which may thereby be made necessary, and the Company agrees to promptly file any amendments to the Registration Statement or the Final Prospectus which may thereby be made necessary, and (ii) the respective numbers of Shares to be purchased by the remaining Underwriters or substituted Underwriters shall be taken as the basis of their underwriting obligation for all purposes of this Agreement. Nothing herein contained shall relieve any defaulting Underwriter of its liability to the Company or any other Underwriter for damages occasioned by its default hereunder. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of any non-defaulting Underwriters or the Company, except that the obligations with respect to expenses to be paid or reimbursed pursuant to Section 5(a)(viii) and Section 7 and Sections 9 through 17, inclusive, shall not terminate and shall remain in full force and effect.

11. Strategic Transaction and/or Private Placement. Notwithstanding anything set forth herein, the Company shall be permitted to engage Torreya Partners for the purposes of consummating a strategic transaction and/or private placement with high net worth investors and family offices.

12. Notices. All notices and communications hereunder shall be in writing and mailed or delivered or by telephone or telegraph if subsequently confirmed in writing, (a) if to the Representative, Aegis Capital Corp., 810 Seventh Avenue, 18th Floor, New York, NY 10019, Attention: Global Equity Markets, with a copy to Aegis Capital Corp., 810 Seventh Avenue, 18th Floor, New York, NY 10019, Attention: Syndicate, and to Sichenzia Ross Ference LLP, 1185 Avenue of the Americas, 37th Floor, New York, NY 10036, Attention: Gregory Sichenzia, and (b) if to the Company, to the Company's agent for service as such agent's address appears on the cover page of the Registration Statement with a copy to Shepard, Mullin, Richter & Hampton LLP, 30 Rockefeller Plaza, New York, NY 10112-0015, Attention: Jeffrey Fessler.

13. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 7. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term "successors and assigns" as herein used shall not include any purchaser, as such purchaser, of any of the Shares from any Underwriters.

14. Absence of Fiduciary Relationship. The Company acknowledges and agrees that: (a) each Underwriter has been retained solely to act as underwriter in connection with the sale of the Shares and that no fiduciary, advisory or agency relationship between the Company and any Underwriter has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Underwriter has advised or is advising the Company on other matters; (b) the price and other terms of the Shares set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Underwriters and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Underwriters and their affiliates are engaged in a broad range of transactions that may involve interests that differ from those of the Company and that no Underwriter has any obligation to disclose such interest and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and (d) it has been advised that each Underwriter is acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of such Underwriter, and not on behalf of the Company.

15. Amendments and Waivers. No supplement, modification or waiver of this Agreement shall be binding unless executed in writing by the party to be bound thereby. The failure of a party to exercise any right or remedy shall not be deemed or constitute a waiver of such right or remedy in the future. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (regardless of whether similar), nor shall any such waiver be deemed or constitute a continuing waiver unless otherwise expressly provided.

16. Partial Unenforceability. The invalidity or unenforceability of any section, paragraph, clause or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph, clause or provision.

17. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

18. Submission to Jurisdiction. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. EACH OF THE COMPANY (ON BEHALF OF ITSELF AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS) AND THE UNDERWRITER HEREBY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, THE REGISTRATION STATEMENT, THE TIME OF SALE DISCLOSURE PACKAGE, ANY PROSPECTUS AND THE FINAL PROSPECTUS.

19. Counterparts. This Agreement may be executed and delivered (including by facsimile transmission or electronic mail) in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

[*Signature Page Follows*]

Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the several Underwriters in accordance with its terms.

Very truly yours,

GREENWICH LIFESCIENCES, INC.

By: _____
Name: _____
Title: _____

Confirmed as of the date first above-mentioned
by the Representative of the several Underwriters.

AEGIS CAPITAL CORP.

By: _____
Name: _____
Title: _____

[Signature page to Underwriting Agreement]

SCHEDULE I

Name	Number of Firm Shares to be Purchased	Number of Option Shares to be Purchased
Aegis Capital Corp.		
Total		

SCHEDULE II

Final Term Sheet

Issuer:	GREENWICH LIFESCIENCES, INC. (the "Company")
Symbol:	GLSI
Securities:	_____ shares of common stock, par value $0.001 per share (the "Common Stock"), of the Company.
Over-allotment option:	_____ shares of Common Stock
Public offering price:	$____ per share of Common Stock
Underwriting discount:	$_____ per share of Common Stock
Non-accountable expense allowance:	$_____ per share of Common Stock
Expected net proceeds:	Approximately $_____ ($_____ if the overallotment option is exercised in full) (after deducting the underwriting discount and estimated offering expenses payable by the Company).
Trade date:	_____, 2020
Settlement date:	_____, 2020
Underwriters:	Aegis Capital Corp.

SCHEDULE III
Free Writing Prospectus

[Free writing prospectus filed on _____, 2020.]

SCHEDULE IV

Snehal Patel
F. Joseph Daugherty
Jaye Thompson
David McWilliams
Eric Rothe
Kenneth Hallock

EXHIBIT A

Form of Representative's Warrant Agreement

EXHIBIT B

Form of Lock-Up Agreement

_____, 2020

Aegis Capital Corp.
810 Seventh Avenue, 18th Floor New York, NY 10019

As Representative of the several Underwriters named on Schedule 1 to the Underwriting Agreement referenced below

Ladies and Gentlemen:

The undersigned understands that Aegis Capital Corp. (the "**Representative**"), proposes to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Greenwich LifeSciences, Inc., a Delaware corporation (the "**Company**"), providing for the public offering (the "**Public Offering**") of shares of common stock, par value $0.001 per share, of the Company (the "**Common Shares**").

To induce the Representative to continue its efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representative, the undersigned will not, during the period commencing on the date hereof and ending one hundred eighty (180) days after the effective date of the Registration Statement on Form S-1 relating to the Public Offering (the "**Lock-Up Period**"), (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the "**Lock-Up Securities**"); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities. Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer Lock-Up Securities without the prior written consent of the Representative in connection with (a) transactions relating to Lock-Up Securities acquired in open market transactions after the completion of the Public Offering; provided that no filing under Section 13 or Section 16(a) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or other public announcement shall be required or shall be voluntarily made in connection with subsequent sales of Lock-Up Securities acquired in such open market transactions; (b) transfers of Lock-Up Securities as a *bona fide* gift, by will or intestacy or to a family member or trust for the benefit of the undersigned (for purposes of this lock-up agreement, "family member" means any relationship by blood, marriage or adoption, not more remote than first cousin); (c) transfers of Lock-Up Securities to a charity or educational institution; (d) if the undersigned is a corporation, partnership, limited liability company or other business entity, (i) any transfers of Lock-Up Securities to another corporation, partnership or other business entity that controls, is controlled by or is under common control with the undersigned or (ii) distributions of Lock-Up Securities to members, partners, stockholders, subsidiaries or affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned; (e) if the undersigned is a trust, to a trustee or beneficiary of the trust; provided that in the case of any transfer pursuant to the foregoing clauses (b), (c) (d) or (e), (i) any such transfer shall not involve a disposition for value, (ii) each transferee shall sign and deliver to the Representative a lock-up agreement substantially in the form of this lock-up agreement and (iii) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made during the Lock-Up Period; (f) the receipt by the undersigned from the Company of Common Shares upon the vesting of restricted stock awards or stock units or upon the exercise of options to purchase the Company's Common Shares issued under an equity incentive plan of the Company or an employment arrangement described in the Pricing Prospectus (as defined in the Underwriting Agreement) (the "**Plan Shares**") or the transfer or withholding of Common Shares or any securities convertible into Common Shares to the Company upon a vesting event of the Company's securities or upon the exercise of options to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax obligations of the undersigned in connection with such vesting or exercise, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Shares during the Lock-Up Period, the undersigned shall include a statement in such schedule or report to the effect that the purpose of such transfer was to cover tax withholding obligations of the undersigned in connection with such vesting or exercise and, provided further, that the Plan Shares shall be subject to the terms of this lock-up agreement; (g) the transfer of Lock-Up Securities pursuant to agreements described in the Pricing Prospectus under which the Company has the option to repurchase such securities or a right of first refusal with respect to the transfer of such securities, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Shares during the Lock-Up Period, the undersigned shall include a statement in such schedule or report describing the purpose of the transaction; (h) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Lock-Up Securities, provided that (i) such plan does not provide for the transfer of Lock-Up Securities during the Lock-Up Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such public announcement or filing shall include a statement to the effect that no transfer of Lock-Up Securities may be made under such plan during the Lock-Up Period; (i) the transfer of Lock-Up Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period, and provided further, that any filing under Section 13 or Section 16(a) of the Exchange Act that is required to be made during the Lock-Up Period as a result of such transfer shall include a statement that such transfer has occurred by operation of law; and (j) the transfer of Lock- Up Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the Common Shares involving a change of control (as defined below) of the Company after the closing of the Public Offering and approved by the Company's board of directors; provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Securities owned by the undersigned shall remain subject to the restrictions contained in this lock-up agreement. For purposes of clause (j) above, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d- 5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Lock-Up Securities except in compliance with this lock-up agreement.

If the undersigned is an officer or director of the Company, (i) the undersigned agrees that the foregoing restrictions shall be equally applicable to any issuer-directed or "friends and family" securities that the undersigned may purchase in the Public Offering; (ii) the Representative agrees that, at least three (3) business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Lock-Up Securities, the Representative will notify the Company of the impending release or waiver; and (iii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two (2) business days before the effective date of the release or waiver. Any release or waiver granted by the Representative hereunder to any such officer or director shall only be effective two (2) business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer of Lock-Up Securities not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of such transfer.

The undersigned understands that the Company and the Representative are relying upon this lock-up agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this lock-up agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

The undersigned understands that, if the Underwriting Agreement is not executed by September 14, 2020 or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Shares to be sold thereunder, then this lock-up agreement shall be void and of no further force or effect.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Representative.

Very truly yours,

(Name - Please Print)

_____

(Signature)

_____

_____

(Name of Signatory, in the case of entities - Please Print)

_____

(Title of Signatory, in the case of entities - Please Print)

Address: _____

_____

SECOND AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
GREENWICH LIFESCIENCES, INC.

GREENWICH LIFESCIENCES, INC. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify as follows:

A. The name of the Corporation is Greenwich LifeSciences, Inc.

B. The original Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on August 29, 2006 under the name Norwell, Inc.

C. This Second Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, and has been duly approved by the written consent of the stockholders of the Corporation in accordance with Section 228 of the General Corporation Law of the State of Delaware.

D. The Certificate of Incorporation of the Corporation, is hereby amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is Greenwich LifeSciences, Inc. (the "Corporation")

SECOND: The address of the Corporation's registered office in the state of Delaware is 2711 Centerville Road, Suite 400, City of Wilmington, County of New Castle, Delaware 19808. The name of the registered agent at such address is The Company Corporation.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law (the "DGCL").

FOURTH: The total number of shares of capital stock that the Corporation shall have authority to issue is 110,000,000 shares, consisting of 100,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 10,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock").

4.1 Common Stock. A statement of the designations, powers, preferences, rights, qualifications, limitations and restrictions in respect to the shares of Common Stock is as follows:

(a) Dividends. The Board of Directors of the Corporation may cause dividends to be paid to the holders of shares of Common Stock out of funds legally available for the payment of dividends by declaring an amount per share as a dividend. When and as dividends are declared on the Common Stock, whether payable in cash, in property or in shares of stock or other securities of the Corporation, the holders of Common Stock shall be entitled to share ratably according to the number of shares of Common Stock held by them, in such dividends.

(b) Liquidation Rights. Subject to the terms of any resolution or resolutions adopted by the Board of Directors pursuant to Section 4.2 of this ARTICLE FOURTH, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation, the holders of Common Stock shall be entitled to share ratably, according to the number of shares of Common Stock held by them, in all remaining assets of the Corporation available for distribution to its stockholders.

(c) Voting Rights. Except as otherwise provided in this Second Amended and Restated Certificate of Incorporation or required by applicable law, the holders of Common Stock shall be entitled to vote on each matter on which the stockholders of the Corporation shall be entitled to vote, and each holder of Common Stock shall be entitled to one vote for each share of such stock held by him. Notwithstanding the foregoing, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Second Amended and Restated Certificate of Incorporation (including any resolution adopted pursuant to Section 4.2 of this ARTICLE FOURTH relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Second Amended and Restated Certificate of Incorporation (including any resolution adopted pursuant to Section 4.2 of this ARTICLE FOURTH relating to any series of Preferred Stock).

4.2 Preferred Stock. The Board of Directors is authorized, subject to any limitation prescribed by law, to adopt one or more resolutions to provide for the issuance of the shares of Preferred Stock in one or more series, and by filing a certificate pursuant to applicable Delaware law to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, irrespective of the provisions of Section 242(b)(2) of the DGCL and without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any resolution adopted pursuant to this Section 4.2.

The authority of the Board of Directors with respect to each series shall include, but not be limited to, determination of the following:

(a) The number of shares constituting the series and the distinctive designation of the series;

(b) The dividend rate (or the method of calculation of dividends) on the shares of the series, whether dividends will be cumulative, and if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of the series;

(c) Whether the series shall have voting rights, in addition to the voting rights required by law, and if so, the terms of such voting rights;

(d) Whether the series shall have conversion rights, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the Board of Directors shall determine;

(e) Whether or not the shares of that series shall be redeemable or exchangeable, and, if so, the terms and conditions of such redemption or exchange, as the case may be, including the date or dates upon or after which they shall be redeemable or exchangeable, as the case may be, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

(f) Whether the series shall have a sinking fund for the redemption or purchase of shares of that series, and if so, the terms and amount of such sinking fund;

(g) The rights of the shares of the series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Corporation, and the relative rights or priority, if any, of payment of shares of the series; and

(h) Any other relative rights, preferences, powers and limitations of that series.

Except for any difference so provided by the Board of Directors, the shares of Preferred Stock will rank on parity with respect to the payment of dividends and to the distribution of assets upon liquidation.

FIFTH:

5.1 Location for Stockholder Meetings. Meetings of stockholders may be held within or outside the state of Delaware or may be held solely by means of remote communication in accordance with the DGCL.

5.3 Special Stockholders Meetings. Except as otherwise required by law, special meetings of the Corporation's stockholders may be called only by (i) the Board of Directors pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, (ii) the Chairman of the Board, if one is elected, or (iii) the Chief Executive Officer. Only those matters set forth in the notice, of the special meeting may be considered or acted upon at such special meeting, unless otherwise provided by law. Notwithstanding the foregoing, whenever holders of one or more series of Preferred Stock shall have the right, voting separately as a class or series, to elect directors, such holders may call, pursuant to the terms of the resolution or resolutions adopted by the Board of Directors pursuant to ARTICLE FOURTH hereto, special meetings of holders of such Preferred Stock.

SIXTH:

6.1 Number of Directors. The number of directors of the Corporation shall be fixed from time to time by the vote of a majority of the entire Board of Directors, except as may be provided by the resolution or resolutions adopted by the Board of Directors of the Corporation in respect of Preferred Stock adopted pursuant to ARTICLE FOURTH hereto, but such number shall in no case be less than one (1) nor more than fifteen (15). Any such determination made by the Board of Directors shall continue in effect unless and until changed by the Board of Directors, but no such changes shall affect the term of any directors then in office.

6.2 Term of Office; Vacancies. Each director shall hold office until a successor is duly elected and qualified or until the director's earlier death, resignation, disqualification or removal. Subject to the rights of the holders of one or more series of Preferred Stock, voting separately by class or series, to elect directors pursuant to the terms of one or more series of Preferred Stock, the election of directors shall be determined by a plurality of the votes cast by the stockholders present in person or represented by proxy at the meeting and entitled to vote thereon. Any vacancies and newly created directorships resulting from an increase in the number of directors shall be filled exclusively by a majority of the directors then in office, even if less than a quorum, and shall hold office until the next stockholder's meeting at which directors are elected and his successor is elected and qualified or until his earlier death, resignation, retirement, disqualification or removal from office.

6.3 Removal. Subject to Section 6.5 hereof, any or all of the directors may be removed from office at any time, but only for cause and only by the affirmative vote of holders of a majority of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

6.4 No Written Ballot. Election of directors need not be by written ballot, unless the By-laws of the Corporation provide otherwise.

6.5 Preferred Stock Directors. Notwithstanding the foregoing, whenever the holders of one or more series of Preferred Stock shall have the right, voting separately as a class or series, to elect directors, the election, term of office, filling of vacancies, removal and other features of such directorships shall be governed by the terms of the resolution or resolutions adopted by the Board of Directors pursuant to ARTICLE FOURTH applicable thereto, and each director so elected shall not be subject to the provisions of this ARTICLE SIXTH unless otherwise provided therein.

SEVENTH: For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation and of its directors and of its stockholders or any class thereof, as the case may be, it is further provided:

(1) The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

(2) The Board of Directors shall have the power to make, alter, amend, change, add to or repeal the By-laws of the Corporation.

(3) In addition to the powers and authority hereinbefore or by statute expressly conferred upon them, the directors are hereby empowered to exercise all such powers and do all such acts and things as maybe exercised or done by the Corporation; subject, nevertheless, to the provisions of the DGCL or this Second Amended and Restated Certificate of Incorporation.

(4) Any action permitted or required to be taken by the Board of Directors pursuant to this Second Amended and Restated Certificate of Incorporation may be taken by an authorized committee thereof, except as expressly prohibited by the DGCL or the By-laws.

EIGHTH: A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. Any repeal or modification of this paragraph shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

NINTH: The Corporation reserves the right to repeal, alter or amend this Second Amended and Restated Certificate of Incorporation in the manner now or hereafter prescribed by statute.

TENTH: The Corporation shall, to the fullest extent permitted by Section 145 of the DGCL, indemnify and advance expenses to (a) its directors and officers and (b) any person who at the request of the Corporation is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise from and against any and all of the expenses, liabilities or other matters referred to in or covered by said section as amended or supplemented (or any successor); provided, however, that, except with respect to proceedings to enforce rights to indemnification, the Corporation shall not indemnify any director, officer or such person in connection with a proceeding (or part thereof) initiated by such director, officer or such person unless such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation. The Corporation, by action of its Board of Directors, may provide indemnification or advance expenses to employees and agents of the Corporation or other persons only on such terms and conditions and to the extent determined by its Board of Directors in its sole and absolute discretion. The indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in their official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person. No amendment to or repeal of this Article TENTH shall adversely affect any right or protection of a director, officer or such other indemnified person of the Corporation existing at the time of, or increase the liability of any director, officer or such other indemnified person of the Corporation with respect to any acts or omissions of such director, officer or such other indemnified person occurring prior to, such amendment or repeal.

[Signature Page Follows]

IN WITNESS WHEREOF, this Second Amended and Restated Certificate of Incorporation has been executed on this [ ] day of [ ], 2020

By: _____
Name:
Title:

SECOND AMENDED AND RESTATED

BY-LAWS

of

Greenwich LifeSciences, Inc.

PREAMBLE

These Second Amended and Restated By-laws (these "By-laws") are subject to, and governed by, the Delaware General Corporation Law (the "DGCL") and the Second Amended and Restated Certificate of Incorporation (the "Certificate") of Greenwich LifeSciences, Inc., a Delaware corporation (the "Corporation"). In the event of a direct conflict between the provisions of these By-laws and the mandatory provisions of the DGCL or the provisions of the Certificate, such provisions of the DGCL or the Certificate, as the case may be, will be controlling.

ARTICLE 1
Offices

SECTION 1.1 Office

The registered office of the Corporation in the State of Delaware shall be at the location determined from time to time by the Corporation's Board of Directors (the "Board"), and the registered agent in charge thereof shall be as determined by the Board.

SECTION 1.2 Other Offices

The Corporation may also have an office or offices at any other place or places within or outside the State of Delaware.

ARTICLE 2
Meetings of Stockholders

SECTION 2.1 Annual Meetings

The annual meeting of the stockholders for the election of directors, and for the transaction of such other business as may properly come before the meeting, shall be held at such place (if any), date and hour as shall be fixed by the Board, within or without the State of Delaware, and designated in the notice or waiver of notice thereof.

SECTION 2.2 Special Meetings

Except as otherwise required by law, special meetings of the stockholders may be called only in accordance with the provisions of the Certificate.

SECTION 2.3 Notice of Meetings

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Unless otherwise required by the Certificate or applicable law, the written notice of any meeting shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. When a meeting is adjourned to another time or place, unless these By-laws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting the Corporation may transact any business which might have been transacted at the original meeting.

SECTION 2.4 Quorum

At each meeting of the stockholders, except where otherwise provided by the Certificate, these By-laws, or as otherwise required by law, the holders of at least a majority of the voting power of the issued and outstanding shares of stock of the Corporation entitled to vote at such meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business. Where a separate vote by a class or classes or series is required, the holders of at least one-third of the voting power of the issued and outstanding shares of such class or classes or series, present in person or by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. When a quorum is present or represented at any meeting, the affirmative vote of a majority of the votes cast affirmatively or negatively on a matter submitted for stockholder action shall decide such matter unless the matter is one upon which, by express provision of law, the Certificate, these By-laws or, with respect to a class or series of Preferred Stock, the terms of the resolution or resolutions adopted by the Board pursuant to ARTICLE FOURTH of the Certificate, a different vote is required, in which case such express provision shall govern and control the decision of such matter. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

SECTION 2.5 Organization

At each meeting of the stockholders, one of the following shall act as chairman of the meeting and preside thereat, in the following order of precedence:

(a) the Chairman;

(b) the Chief Executive Officer;

(c) any Vice President;

(d) any officer of the Corporation designated by the Board to act as chairman of such meeting and to preside thereat; or

(e) a stockholder of record who shall be chosen chairman of such meeting by the holders of a majority in voting power of the stock held by the stockholders present in person or by proxy and entitled to vote thereat.

The Secretary or, if he shall be presiding over such meeting in accordance with the provisions of this Section 5 or if he shall be absent from such meeting, the person (who shall be an Assistant Secretary, if an Assistant Secretary has been appointed and is present) whom the chairman of such meeting shall appoint, shall act as secretary of such meeting and keep the minutes thereof.

SECTION 2.6 Order of Business

Each of the chairman of the meeting and the Board shall have the authority to adopt and enforce rules providing for the orderly conduct of a stockholder meeting and the safety of those in attendance, including, without limitation, the authority to: (i) determine when the polls will open and close on items submitted for stockholder action; (ii) fix the time allotted for consideration of each agenda item and for questions and comments by persons in attendance; (iii) adopt rules for determining who may pose questions and comments during the meeting; (iv) adopt rules for determining who may attend the meeting; and (v) adopt procedures (if any) requiring attendees to provide the Corporation advance notice of their intent to attend the meeting. The chairman of the meeting may adjourn or recess any meeting of stockholders, whether pursuant to these By-laws or otherwise, and notice of such adjournment or recess need be given only if required by law.

SECTION 2.7 Voting

Except as may otherwise be required by law or these By-laws, stockholders shall have the voting rights specified in the Certificate.

SECTION 2.8 Voting Procedures and Inspection of Elections

(a) The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his ability.

(b) The inspectors shall (i) ascertain the number of shares outstanding and the voting power of each, (ii) determine the shares represented at a meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

(c) The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless Court of Chancery of the State of Delaware, upon application by a stockholder, shall determine otherwise.

(d) In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in accordance with Section 211(e) or Section 212(c)(2) of the DGCL, or any information provided pursuant to Section 211(a)(2)b.(i) or (iii) of the DGCL, ballots and the regular books and records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted in this Section 8, the inspectors at the time they make their certification pursuant to subsection (b)(v) of this Section 8 shall specify the precise information considered by them including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

SECTION 2.9 Advance Notification of Proposals at Stockholders' Meetings

(a) Annual Meeting.

(i) Nominations of persons for election to the Board and the proposal of business other than nominations to be considered by the stockholders may be made at an annual meeting of stockholders only (A) pursuant to, and in accordance with, the Corporation's notice of meeting (or any supplement thereto), (B) by or at the direction of the Board or any authorized committee thereof or (C) by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 9 is delivered to the Secretary, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 9(a). For the avoidance of doubt, the foregoing clause (C) shall be the exclusive means for a stockholder to make director nominations or propose other business (other than a proposal included in the Corporation's proxy materials pursuant to and in compliance with Rule 14a-8 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), at an annual meeting of stockholders.

(ii) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (C) of the foregoing paragraph, the stockholder must have given timely notice thereof in writing to the Secretary and, in the case of business other than nominations, such business must be a proper subject for stockholder action and the stockholder and the beneficial owner, if any, on whose behalf any such proposal or nomination is made, must have acted in accordance with the representations set forth in the Solicitation Statement required by these By-laws. To be timely under this Section 9(a), a stockholder's notice must be delivered to the Secretary at the principal executive offices of the Corporation not later than the Close of Business (as defined below) on the 90th day nor earlier than the Close of Business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the Close of Business on the 120th day prior to such annual meeting and not later than the Close of Business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which Public Announcement (as defined in Section 9(c)(ii) below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or recess of an annual meeting, or a postponement of an annual meeting for which notice has been given or with respect to which there has been a Public Announcement of the date of the meeting, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. Such stockholder's notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or reelection to the Board (1) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to and in accordance with Regulation 14A under the Exchange Act, and (2) the information required to be submitted by nominees pursuant to Section 10 of this Article 2;

(B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these By-laws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any substantial interest (within the meaning of Item 5 of Exchange Act Schedule 14A) in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made;

(C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made or the other business is proposed:

(1) the name and address of such stockholder, as they appear on the Corporation's books, and the name and address of such beneficial owner,

(2) the number of shares of Common Stock and any series of Preferred Stock which are owned of record by such stockholder and such beneficial owner as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the number of shares of Common Stock and any series of Preferred Stock owned of record by the stockholder and such beneficial owner as of the record date for the meeting (except as otherwise provided in Section 9(a)(iii) below), and

(3) a representation that the stockholder intends to appear in person or by proxy at the meeting to make such nomination or propose such business;

(D) as to the stockholder giving the notice or, if the notice is given on behalf of a beneficial owner on whose behalf the nomination is made or the other business is proposed, as to such beneficial owner, and if such stockholder or beneficial owner is an entity, as to each director, executive, managing member or control person of such entity (any such individual or control person, a "Control Person"):

(1) the number of shares of Common Stock and any series of Preferred Stock which are Beneficially Owned (as defined in Section 9(c)(ii) below) by such stockholder or beneficial owner and by any Control Person as of the date of the notice, and the stockholder's agreement to notify the Corporation in writing within five business days after the record date for such meeting of the number of shares of Common Stock and any series of Preferred Stock Beneficially Owned by such stockholder or beneficial owner and by any Control Person as of the record date for the meeting (except as otherwise provided in Section 9(a)(iii) below),

(2) a description of any agreement, arrangement or understanding with respect to the nomination or other business between or among such stockholder, beneficial owner or Control Person and any other person, including, without limitation, any agreements that would be required to be disclosed pursuant to Item 5 or Item 6 of Exchange Act Schedule 13D (regardless of whether the requirement to file a Schedule 13D is applicable) and the stockholder's agreement to notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting (except as otherwise provided in Section 9(a)(iii) below),

(3) a description of any agreement, arrangement or understanding (including, without limitation, any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder, beneficial owner or Control Person, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the share price of the Common Stock or any series of Preferred Stock, or maintain, increase or decrease the voting power of the stockholder, beneficial owner or Control Person with respect to any Common Stock or any series of Preferred Stock, and the stockholder's agreement to notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting (except as otherwise provided in Section 9(a)(iii) below),

(4) a representation whether the stockholder or the beneficial owner, if any, will engage in a solicitation within the meaning of Exchange Act Rule 14a-1(l) with respect to the nomination or other business and, if so, the name of each participant (as defined in Item 4 of Exchange Act Schedule 14A) in such solicitation and whether such person intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Common Stock or any series of Preferred Stock required to approve or adopt the business to be proposed (in person or by proxy) by the stockholder (a "Solicitation Statement").

(iii) Notwithstanding anything in Section 9(a)(ii) above or Section 9(b) below to the contrary, if the record date for determining the stockholders entitled to vote at any meeting of stockholders is different from the record date for determining the stockholders entitled to notice of the meeting, a stockholder's notice required by this Section 9 shall set forth a representation that the stockholder will notify the Corporation in writing within five business days after the record date for determining the stockholders entitled to vote at the meeting, or by the business day immediately preceding the date of the annual meeting (whichever is earlier), of the information required under clauses (ii)(C)(2) and (ii)(D)(1)-(3) of this Section 9(a), and such information when provided to the Corporation shall be current as of the record date for determining the stockholders entitled to vote at the meeting.

(b) Special Meeting.

Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting (i) by or at the direction of the Board or any authorized committee thereof or (ii) provided that one or more directors are to be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 9(b) is delivered to the Secretary, who is entitled to vote at the meeting and upon such election and who delivers a written notice setting forth the information required by Section 9(a) above. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors, any stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting, if the notice required by this Section 9(b) shall be delivered to the Secretary at the principal executive offices of the Corporation not earlier than the Close of Business on the 120th day prior to such special meeting and not later than the Close of Business on the later of the 90th day prior to such special meeting or the 10th day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall an adjournment, recess or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) General.

(i) Except as otherwise required by law, only such persons who are nominated in accordance with the procedures set forth in Section 9(a)(i) and Section 9(b) above shall be eligible to be elected at any meeting of stockholders of the Corporation to serve as directors and only such other business shall be conducted at an annual meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in Section 9(a)(i) above. Except as otherwise required by law, each of the Board or the chairman of the meeting shall have the power to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 9. If any proposed nomination or other business is not in compliance, then, except as otherwise required by law, the chairman of the meeting shall have the power to declare that such nomination shall be disregarded or that such other business shall not be transacted. Notwithstanding the foregoing provisions of this Section 9, unless otherwise required by law or otherwise determined by the chairman of the meeting or the Board, if the stockholder does not provide the information required under clauses (a)(ii)(C)(2) and (a)(ii)(D)(1)-(3) of this Section 9 to the Corporation within the time frames specified herein, or if the stockholder (or a Qualified Representative of the stockholder (as defined below)) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or other business, such nomination shall be disregarded and such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 9, to be considered a "Qualified Representative" of a stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or authorized by a writing executed by such stockholder (or a reliable reproduction or electronic transmission of the writing) delivered to the Corporation prior to the making of such nomination or proposal at such meeting by such stockholder stating that such person is authorized to act for such stockholder as proxy at the meeting of stockholders.

(ii) For purposes of this Section 9, the "Close of Business" shall mean 5:00 p.m. local time at the principal executive offices of the Corporation on any calendar day, whether or not the day is a business day, and a "Public Announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Corporation with the SEC pursuant to Sections 13, 14 or 15(d) of the Exchange Act. For purposes of clause (a)(ii)(D)(1) of this Section 9, shares shall be treated as "Beneficially Owned" by a person if the person beneficially owns such shares, directly or indirectly, within the meaning of Exchange Act Rule 13d-3, or has or shares pursuant to any agreement, arrangement or understanding (whether or not in writing): (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time or the fulfillment of a condition or both), (B) the right to vote such shares, alone or in concert with others and/or (C) investment power with respect to such shares, including the power to dispose of, or to direct the disposition of, such shares.

SECTION 2.10 Submission of Information by Director Nominees.

(a) To be eligible to be a nominee for election or re-election as a director of the Corporation, a person must deliver to the Secretary at the principal executive offices of the Corporation the following information:

(i) a written representation and agreement, which shall be signed by such person and pursuant to which such person shall represent and agree that such person: (A) consents to serving as a director if elected and (if applicable) to being named in the Corporation's proxy statement and form of proxy as a nominee, and currently intends to serve as a director for the full term for which such person is standing for election; (B) is not and will not become a party to any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity: (1) as to how the person, if elected as a director, will act or vote on any issue or question that has not been disclosed to the Corporation; or (2) that could limit or interfere with the person's ability to comply, if elected as a director, with such person's fiduciary duties under applicable law; (C) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director or nominee that has not been disclosed to the Corporation; and (D) if elected as a director, will comply with all of the Corporation's corporate governance, conflict of interest, confidentiality, and stock ownership and trading policies and guidelines, and any other Corporation policies and guidelines applicable to directors (which will be provided to such person promptly following a request therefor); and

(ii) all completed and signed questionnaires required of the Corporation's directors (which will be provided to such person promptly following a request therefor).

(b) A nominee for election or re-election as a director of the Corporation shall also provide to the Corporation such other information as it may reasonably request. The Corporation may request such additional information as necessary to permit the Corporation to determine the eligibility of such person to serve as a director of the Corporation, including information relevant to a determination whether such person can be considered an independent director.

(c) Notwithstanding any other provision of these By-laws, if a stockholder has submitted notice of an intent to nominate a candidate for election or re-election as a director pursuant to Section 9 of this Article 2, the questionnaires described in Section 10(a)(ii) above and the additional information described in Section 10(b) above shall be considered timely if provided to the Corporation promptly upon request by the Corporation, but in any event within five business days after such request, and all information provided pursuant to this Section 11 shall be deemed part of the stockholder's notice submitted pursuant to Section 9 of this Article 2.

SECTION 2.11 Advisory Stockholder Votes

In order for the stockholders to adopt or approve any precatory proposal submitted to them for the purpose of requesting the Board to take certain actions, a majority of the outstanding stock of the Corporation entitled to vote thereon must be voted in favor of the proposal.

SECTION 2.12 List of Stockholders

The Corporation shall prepare, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, if the record date for determining the stockholders entitled to vote is less than ten days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing contained in this Section 12 shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then such list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

ARTICLE 3
Board of Directors

SECTION 3.1 General Powers

The business, property and affairs of the Corporation shall be managed by or under the direction of the Board, which may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law or by the Certificate directed or required to be exercised or done by the stockholders.

SECTION 3.2 Number and Term of Office

The number of directors shall be fixed in accordance with the Certificate. Directors need not be stockholders. Each director shall hold office until his successor is elected and qualified, or until his earlier death, resignation, retirement, disqualification or removal in the manner hereinafter provided. No decrease in the number of directors shall have the effect of shortening the term of any incumbent director.

SECTION 3.3 Election of Directors

At each meeting of the stockholders for the election of directors at which a quorum is present, the persons receiving the greatest number of votes, up to the number of directors to be elected, of the stockholders present in person or by proxy and entitled to vote thereon, shall be the directors; provided that for purposes of such vote no stockholder shall be allowed to cumulate his votes.

SECTION 3.4 Resignation and Vacancies

Any director may resign at any time by giving written notice (or notice by electronic transmission) to the Board, the Chairman, the Chief Executive Officer or the Secretary. Such resignation shall take effect at the time specified therein (which may be upon the happening of an event or events specified therein) or, if the time be not specified, upon delivery thereof; and, unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Except as otherwise required by law, vacancies on the Board and newly created directorships will be filled in accordance with the Certificate.

SECTION 3.5 Meetings

(a) **Regular Meetings**. As soon as practicable after each annual election of directors, the Board shall meet for the purpose of organization and the transaction of other business, unless it shall have transacted all such business by written consent pursuant to Section 6 of this Article 3.

(b) **Special Meetings**. Other meetings of the Board shall be held at such times and places as the Board, the Chairman, the Chief Executive Officer or any two directors shall from time to time determine.

(c) **Notice of Meetings**. Notice shall be given to each director for each regular and special meeting, including the time and place of such meeting. Unless otherwise indicated in the notice thereof, any and all business may be transacted at a meeting. Notice of each such meeting shall be mailed to each director, addressed to him at his residence or usual place of business, at least two days before the date on which such meeting is to be held, or shall be sent to him at such place by telegraph, cable, wireless or other form of recorded communication or by electronic transmission, or be delivered personally or by telephone not later than the day before the day on which such meeting is to be held.

(d) **Place of Meetings**. The Board may hold its meetings at such place or places (if any) within or outside the State of Delaware as the Board may from time to time determine, or as shall be designated in the respective notices or waivers of notice thereof.

(e) **Quorum and Manner of Acting**. Directors comprising a majority of the total number of authorized directorships shall constitute a quorum for the transaction of business. All matters shall be determined by the affirmative vote of a majority of the directors present at a meeting at which a quorum is present. In the absence of a quorum for any such meeting, a majority of the directors present thereat may adjourn such meeting from time to time until a quorum shall be present and no further notice thereof need be given.

(f) **Organization**. At each meeting of the Board, one of the following shall act as chairman of the meeting and preside thereat, in the following order of precedence:

(1) the Chairman;

(2) the Chief Executive Officer (if a director); or

(3) a person designated by the Board.

The Secretary or, in the case of his absence, any person (who shall be an Assistant Secretary, if an Assistant Secretary has been appointed and is present) whom the chairman of the meeting shall appoint shall act as secretary of such meeting and keep the minutes thereof.

SECTION 3.6 Directors' Consent in Lieu of Meeting

Unless otherwise restricted by the Certificate or these By-laws, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing, or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board, or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this subsection at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

SECTION 3.7 Action by Means of Conference Telephone or Similar Communications Equipment

Any one or more members of the Board or any committee thereof, may participate in a meeting of such Board or committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

SECTION 3.8 Committees

(a) The Board may designate one or more committees, each such committee to consist of one or more directors. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. The Board at any time may change the membership of any committee or amend or rescind the resolution designating the committee. Each committee shall keep a record of proceedings and report the same to the Board to such extent and in such form as the Board may require. Unless otherwise provided in the resolution designating a committee, a majority of all of the members of any such committee may select its Chairman, fix its rules or procedure, fix the time and place of its meetings and specify what notice of meetings, if any, shall be given. Any such committee, to the extent provided in the resolution of the Board, or in these By-laws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to the following matter: (i) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval or (ii) adopting, amending or repealing any by-law of the Corporation.

(b) A majority of the directors then serving on a committee of the Board shall constitute a quorum for the transaction of business by the committee, unless the Certificate or a resolution of the Board requires a greater or lesser number, provided that in no case shall a quorum be less than one-third of the directors then serving on the committee. The vote of the majority of the members of a committee present at a meeting at which a quorum is present shall be the act of the committee, unless the Certificate or a resolution of the Board requires a greater number.

SECTION 3.9 Compensation

The Board shall have the authority to fix the compensation of directors, which may include their expenses, if any, of attendance at each meeting of the Board or of a committee.

SECTION 3.10 Preferred Stock Directors

Notwithstanding the foregoing, whenever the holders of one or more series of Preferred Stock shall have the right, voting separately as a class or series, to elect directors, the election, term of office, filling of vacancies, removal and other features of such directorships shall be governed by the terms of the resolution or resolutions adopted by the Board pursuant to ARTICLE FOURTH of the Certificate applicable thereto, and each director so elected shall not be subject to the provisions of this ARTICLE 3 unless otherwise provided therein.

ARTICLE 4
Officers

SECTION 4.1 Executive Officers

The executive officers of the Corporation shall be determined by the Board and may include a Chairman, a Chief Executive Officer, a Chief Executive Officer, Senior Vice Presidents, Vice Presidents, a Secretary and a Treasurer, and also may include such other officers as the Board may appoint pursuant to Section 3 of this Article 4. Any two or more offices may be held by the same person.

SECTION 4.2 Authority and Duties

All officers, as between themselves and the Corporation, shall have such authority and perform such duties in the management of the Corporation as may be provided in these By-laws or, to the extent so provided, by the Board.

SECTION 4.3 Other Officers

The Corporation may have such other officers, agents and employees as the Board may deem necessary, including one or more Assistant Secretaries, one or more Assistant Treasurers and one or more Vice Presidents, each of whom shall hold office for such period, have such authority, and perform such duties as the Board, the Chairman, or the Chief Executive Officer may from time to time determine. The Board may delegate to any executive officer the power to appoint and define the authority and duties of, or remove, any such officers, agents or employees.

SECTION 4.4 Term of Office, Resignation and Removal

All executive officers shall be elected or appointed by the Board and shall hold office for such term as may be prescribed by the Board. Each executive officer shall hold office until his successor has been elected or appointed and qualified or until his earlier death or resignation or removal in the manner hereinafter provided. The Board may require any executive officer to give security for the faithful performance of his duties.

Any officer may resign at any time by delivering written notice (or notice by electronic transmission) to the Board, the Chairman, the Chief Executive Officer or the Secretary. Such resignation shall take effect at the time specified therein (which may be upon the happening of an event or events specified therein) or, if the time be not specified, at the time notice is given. Except as aforesaid, the acceptance of such resignation shall not be necessary to make it effective.

All officers and agents elected or appointed by the Board shall be subject to removal at any time by the Board with or without cause, subject to any agreements to the contrary.

SECTION 4.5 Vacancies

If the office of Chairman, Chief Executive Officer, Secretary or Treasurer becomes vacant for any reason, the Board shall fill such vacancy, and if any other office becomes vacant, the Board may fill such vacancy. Except as otherwise provided in these By-laws, any officer so appointed or elected by the Board shall serve only until such time as the unexpired term of his predecessor shall have expired and until his successor shall have been duly elected and qualified, unless reelected or reappointed by the Board.

SECTION 4.6 The Chairman

The Chairman of the Board shall perform such duties as shall be assigned to him by the Board from time to time.

SECTION 4.7 The Chief Executive Officer

In the event that the office of Chairman is or becomes vacant, the chief executive officer of the Corporation shall act as Chairman. The Chief Executive Officer shall have general charge and supervision of the operation of the business and affairs of the Corporation. The Chief Executive Officer may authorize, execute and deliver, for and on behalf of the Corporation, deeds, mortgages, bonds, contracts, or other instruments, except when the signing and execution thereof have been expressly delegated by the Board or by these By-laws to some other officer or agent of the Corporation or are required by law to be otherwise signed or executed by some other officer or in some other manner. He shall from time to time make such reports of the affairs of the Corporation as the Board may require and shall perform all other duties incident to the office of Chief Executive Officer and such other duties as may from time to time be assigned to him by the Board or the Chairman.

SECTION 4.8 Senior Vice President or Vice President

In the event of the death of the Chief Executive Officer or his or her inability to act, the Senior Vice President or Vice President, if any (or if there is more than one Senior Vice President or Vice President, the Senior Vice President or Vice President who was designated by the Board as the successor to the Chief Executive Officer, or if no Senior Vice President or Vice President is so designated, the Senior Vice President first elected to such office or if there is no Senior Vice President, the Vice President first elected to such office) shall perform the duties of the Chief Executive Officer, except as may be limited by resolution of the Board, with all the powers of and subject to all the restrictions upon the Chief Executive Officer. Senior Vice Presidents or Vice Presidents shall have, to the extent authorized by the Chief Executive Officer or the Board, the same powers as the Chief Executive Officer to authorize, execute and deliver, for and on behalf of the Corporation, deeds, mortgages, bonds, contracts, or other instruments. Senior Vice President or Vice Presidents shall perform all other duties incident to the office of Senior Vice President or Vice President and such other duties as from time to time may be assigned to them by the Chief Executive Officer or by the Board. The Board may name any Senior Vice President or Vice President as the Chief Operating Officer, Chief Financial Officer or similar title.

SECTION 4.9 The Secretary

The Secretary shall, to the extent practicable, attend all meetings of the Board and all meetings of the stockholders and shall record, or cause to be recorded, the minutes of all proceedings in a book to be kept for that purpose. He may give, or cause to be given, notice of all meetings of the stockholders and of the Board, and shall perform such other duties as may be prescribed by the Board, the Chairman or the Chief Executive Officer, under whose supervision he shall act. He shall keep, or cause to be kept, in safe custody the seal of the Corporation and affix the same to any duly authorized instrument requiring it and, when so affixed, it may be attested by his signature or by the signature of the Treasurer or, if appointed, an Assistant Secretary or an Assistant Treasurer. The Board may give general authority to any other officer to affix the seal of the Corporation and to attest such affixing of the seal. He shall keep in safe custody the certificate books and stockholder records, including registers of the post office address of each stockholder and director, and such other books and records as the Board may direct, and shall perform all other duties incident to the office of Secretary and such other duties as from time to time may be assigned to him by the Board, the Chairman or the Chief Executive Officer.

SECTION 4.10 The Treasurer

The Treasurer shall supervise and be responsible for the care and custody of the corporate funds and other valuable effects, including securities, and shall keep, or cause to be kept, full and accurate accounts of receipts and disbursements in books belonging to the Corporation, and shall deposit, or cause to be deposited, all moneys and other valuable effects in the name and to the credit of the Corporation in such depositories as may be designated by the Board. The Treasurer shall disburse the funds of the Corporation as may be ordered by the Board, taking proper vouchers for such disbursements, and shall render to the Chairman, the Chief Executive Officer and directors, at the regular meetings of the Board, or whenever they may require it, an account of all his transactions as Treasurer and of the financial condition of the Corporation, and shall perform all other duties incident to the office of Treasurer and such other duties as from time to time may be assigned to him by the Board, the Chairman or the Chief Executive Officer.

SECTION 4.10 Chief Financial Officer

The Chief Financial Officer shall be the principal financial officer of the Corporation and shall have such powers and perform such duties as may be assigned by the Board of Directors, the Chairman of the Board, or the Chief Executive Officer.

ARTICLE 5
Contracts, Checks, Drafts, Bank Accounts, Etc.

SECTION 5.1 Execution of Documents

The Board shall designate, by either specific or general resolution, the officers, employees and agents of the Corporation who shall have the power to authorize, execute and deliver, for and on behalf of the Corporation, deeds, contracts, mortgages, bonds, debentures, checks, drafts and other orders for the payment of money and other documents for and in the name of the Corporation, and may authorize such officers, employees and agents to delegate such power (including authority to subdelegate) by written instrument to other officers, employees or agents of the Corporation; and, unless so designated or expressly authorized by these By-laws, no officer, employee or agent shall have any power or authority to bind the Corporation by any contract or engagement, to pledge its credit or to render it liable pecuniarily for any purpose or to any amount.

SECTION 5.2 Deposits

All funds of the Corporation not otherwise employed shall be deposited from time to time to the credit of the Corporation or otherwise as the Board or Treasurer, or any other officer of the Corporation to whom power in this respect shall have been given by the Board, shall select.

SECTION 5.3 Proxies in Respect of Stock or Other Securities of Other Corporations

The Board shall designate the officers of the Corporation who shall have authority from time to time to appoint an agent or agents of the Corporation to exercise in the name and on behalf of the Corporation the powers and rights which the Corporation may have as the holder of stock or other securities in any other corporation, and to vote or consent in respect of such stock or securities. Such designated officers may instruct the person or persons so appointed as to the manner of exercising such powers and rights, and such designated officers may execute or cause to be executed in the name and on behalf of the Corporation and under its corporate seal or otherwise, such written proxies, powers of attorney or other instruments as they may deem necessary or proper in order that the Corporation may exercise its said powers and rights.

ARTICLE 6
Shares and Their Transfer; Fixing Record Date; Waiver of Notice

SECTION 6.1 Certificates for Shares

Subject to Section 6.2, every owner of stock of the Corporation shall be entitled to have a certificate certifying the number and class of shares owned by him in the Corporation, which shall be in such form as shall be prescribed by the Board. Each certificate for shares shall be numbered and issued in consecutive order. Certificates of stock in the Corporation, if any, shall be signed, either manually or in facsimile by two of the Chairman, the Chief Executive Officer, any Vice President, the Treasurer (or an Assistant Treasurer, if appointed), the Secretary (or an Assistant Secretary, if appointed) or any other authorized officers of the Corporation. Where a certificate is countersigned by a transfer agent, other than the Corporation or an employee of the Corporation, or by a registrar, the signatures of the Chairman or the Chief Executive Officer or a Vice President and the Treasurer or an Assistant Treasurer or the Secretary or an Assistant Secretary may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, the certificate may be issued by the Corporation with the same effect as if such officer, transfer agent or registrar were such officer, transfer agent or registrar at the date of its issue. All certificates shall include written notice of any restrictions which may be imposed on the transferability of shares.

SECTION 6.2 Shares without Certificates

The Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Within a reasonable time after the issue or transfer of shares without certificates, the Corporation shall send the stockholder a written statement of the information required by law on the certificates. The written statement shall include written notice of any restrictions which may be imposed on the transferability of such shares.

SECTION 6.3 Transfer of Stock

Upon surrender to the Corporation or the transfer agent of the Corporation of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer, it shall be the duty of the Corporation to issue a new certificate of stock or uncertificated shares in place of any certificate therefor issued by the Corporation to the person entitled thereto, cancel the old certificate and record the transaction in its stock transfer books.

SECTION 6.4 Addresses of Stockholders

Each stockholder shall designate to the Secretary an address at which notices of meetings and all other corporate notices may be served or mailed to him.

SECTION 6.5 Replacement

The Corporation may issue a new certificate of stock or uncertificated shares in place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

SECTION 6.6 Regulations

The Board may make such rules and regulations as it may deem expedient, not inconsistent with these By-laws, concerning the issue, transfer and registration of certificates for stock of the Corporation.

SECTION 6.7 Fixing Date for Determination of Stockholders of Record

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the foregoing provisions of this subsection (a) at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

SECTION 6.8 Waiver of Notice

Whenever notice is required to be given, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate or these By-laws.

ARTICLE 7
Seal

The corporate seal shall be in such form as may be approved from time to time by the Board. The seal may be used by causing it or a facsimile thereof, to be impressed or affixed or in any other manner reproduced.

ARTICLE 8
Fiscal Year

The fiscal year of the Corporation shall be fixed by resolution of the Board.

ARTICLE 9
Indemnification and Insurance

SECTION 9.1 Right to Indemnification

Each person who was, is or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any threatened, pending or completed action, suit, claim or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal (a "proceeding"), by reason of the fact that he or she is or was a director or officer of the Corporation or, that being or having been a director or officer of the Corporation, he or she is or was serving at the request of the Corporation as a director, officer, partner, trustee, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise (an "indemnitee"), whether the basis of a proceeding is alleged action in an official capacity or in any other capacity while serving as a director, officer, partner, trustee, employee or agent, shall be indemnified and held harmless, to the fullest extent permitted by Delaware law, by the Corporation against all losses, claims, damages (compensatory, exemplary, punitive or otherwise), liabilities and expenses (including attorneys' fees, costs, judgments, fines, ERISA excise taxes or penalties, amounts to be paid in settlement and any other expenses) actually and reasonably incurred or suffered by the indemnitee in connection with the proceeding, and the indemnification shall continue as to an indemnitee who has ceased to be a director or officer of the Corporation or a director, officer, partner, trustee, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Except as provided in Section 3 of this Article 9 with respect to proceedings seeking to enforce rights to indemnification, the Corporation shall indemnify the indemnitee in connection with a proceeding (or part of a proceeding) initiated by the indemnitee only if a proceeding (or part of a proceeding) was authorized or ratified by the Board. The right to indemnification conferred in this Article 9 shall be a contract right. The intent of this Article 9 is to grant each indemnitee the maximum indemnification and advancement of expenses as allowed by law, subject to the limitations expressly provided in this Article 9.

SECTION 9.2 Advancement of Expenses

The right to indemnification conferred in this Article 9 shall include the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in defending any proceeding (or part thereof) in advance of its final disposition (an "advancement of expenses"). An advancement of expenses shall be made upon delivery to the Corporation of an undertaking (an "undertaking"), by or on behalf of the indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that the indemnitee is not entitled to be indemnified.

SECTION 9.3 Right of Indemnitee to Bring Suit

If a claim under Sections 1 and 2 of this Article 9 is not paid in full by the Corporation within 60 days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be 20 days, the indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If successful in whole or in part, in any such suit or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of litigating the suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article 9 or otherwise shall be on the Corporation.

SECTION 9.4 Nonexclusivity of Rights

The right to indemnification and the advancement of expenses conferred in this Article9 shall not be exclusive of any other right that any person may have or hereafter acquire under any statute, provision of, the Certificate or By-laws of the Corporation, general or specific action of the Board or stockholders, contract or otherwise.

SECTION 9.5 Insurance, Contracts and Funding

The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, partner, trustee, employee or agent of the Corporation or another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise against any expense, liability or loss, whether or not the Corporation would have the authority or right to indemnify the person against the expense, liability or loss under the DGCL or other law. The Corporation may enter into contracts with any director, officer, partner, trustee, employee or agent of the Corporation in furtherance of the provisions of this Article9 and may create a trust fund, grant a security interest or use other means (including, without limitation, a letter of credit) to ensure the payment of the amounts as may be necessary to effect indemnification as provided in this Article 9.

SECTION 9.6 Indemnification of Employees and Agents of the Corporation

In addition to the rights of indemnification set forth in Section 1 of this Article 9, the Corporation may, by action of the Board, grant rights to indemnification and advancement of expenses to employees and agents or any class or group of employees and agents of the Corporation (a) with the same scope and effect as the provisions of this Article 9 with respect to indemnification and the advancement of expenses of directors and officers of the Corporation, (b) pursuant to rights granted or provided by the DGCL, or (c) as are otherwise consistent with law.

SECTION 9.7 Persons Serving Other Entities

Any person who, while a director or officer of the Corporation, is or was serving (a) as a director, officer, employee or agent of another corporation of which a majority of the shares entitled to vote in the election of its directors is held by the Corporation or (b) as a partner, trustee or otherwise in an executive or management capacity in a partnership, joint venture, trust, employee benefit plan or other enterprise of which the Corporation or a majority owned subsidiary of the Corporation is a general partner or has a majority ownership, shall conclusively be deemed to be so serving at the request of the Corporation and entitled to indemnification and the advancement of expenses under Section 1 or 2 of this Article 9, respectively.

SECTION 9.8 Effect of Amendment or Repeal; Survival.

Any amendment, alteration or repeal of this Article 9 that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit, eliminate, or impair any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment or repeal. The right to indemnification and advancement of expenses under this Article 9 shall be construed as a contractual right of the indemnitees, shall continue as a vested contractual right, even if a person ceases to be a director or officer of the corporation, and shall inure to the benefit of an indemnitee's heirs, executors and administrators.

ARTICLE 10
Amendment

These By-laws may be altered, amended or repealed or new By-laws may be adopted by the Board or by the affirmative vote of the holders of a majority of the voting power of the issued and outstanding shares of stock of the Corporation.

ARTICLE 11
Exclusive Forum

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the DGCL or any provision of the Certificate or these Bylaws, or (iv) any action asserting a claim against the Corporation, its directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction.

Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article 11.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "GREENWICH LIFESCIENCES, INC.", FILED IN THIS OFFICE ON THE TWENTY-SECOND DAY OF JUNE, A.D. 2020, AT 9:21 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

4211497 8100
SR# 20205814181

Authentication: 203149695
Date: 06-22-20

You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Amendment
of
Amended and Restated Certificate of Incorporation
of
Greenwich LifeSciences, Inc.

Under Section 242 of the Delaware General Corporation Law

Greenwich LifeSciences, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation") hereby certifies as follows:

FIRST: The Amended and Restated Certificate of Incorporation of the Corporation as filed on April 19, 2011 is hereby amended by adding the following to the end of Article IV:

ARTICLE IV

"Effective as of4:00 p.m., local time on June 22 2020 (the "Amendment Effective Time"), every 2.67 shares of the Company's Common Stock and Preferred Stock then issued and outstanding, shall, automatically and without any action on the part of the respective holders thereof, be combined, converted and changed into one (1) share of Common Stock and one (1) share of Preferred Stock, respectively, of the Company (the "Reverse Stock Split"). No fractional shares shall be issued upon the Reverse Stock Split. If the Reverse Stock Split would result in the issuance of a fraction of a share of Common Stock or Preferred Stock, as the case may be, the Corporation shall, in lieu of issuing any such fractional share, round up such share to the nearest whole share."

SECOND: The foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the General Corporation law of the State of Delaware by the vote of a majority of each class of outstanding stock of the Corporation entitled to vote thereon.

IN WITNESS WHEREOF, I have signed this Certificate this 22nd day of June, 2020

/s/ Snehal Patel
Snehal Patel, Chief Executive Officer

State of Delaware
Secretary of State
Division of Corporations
Delivered 09:21 AM 06/22/2020
FILED 09:21 AM 06/22/2020
SR 20205814181 - File Number 4211497

NUMBER

SHARES

GREENWICH LIFESCIENCES, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SEE REVERSE FOR CERTAIN DEFINITIONS

COMMON STOCK

CUSIP 396879 10 8

THIS CERTIFIES THAT:

IS THE OWNER OF

FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF $0.001 PAR VALUE EACH OF

GREENWICH LIFESCIENCES, INC.

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this certificate duly endorsed or assigned. This certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Certificate of Incorporation and Bylaws of the Corporation, as now or hereafter amended.

This certificate is not valid until countersigned by the Transfer Agent.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

DATED:

GREENWICH LIFESCIENCES, INC. CORPORATE SEAL 2006 DELAWARE

COUNTERSIGNED:

PHILADELPHIA STOCK TRANSFER, INC.
2320 HAVERFORD RD., SUITE 230, ARDMORE, PA 19003
TRANSFER AGENT

BY:

AUTHORIZED SIGNATURE

SPECIMEN NOT NEGOTIABLE

CHAIRMAN OF BOARD

CHIEF EXECUTIVE OFFICER

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common	*UNIF GIFT MIN ACT - .....Custodian.....*
TEN ENT - as tenants by the entireties	*(Cust) (Minor)*
JT TEN - as joint tenants with right of survivorship and not as tenants in common	*under Uniform Gifts to Minors Act .....*
	(State)

Additional abbreviations may also be used though not in the above list.

For Value Received,_____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ *Shares*

of the stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ *Attorney*

to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____

The Signature(s) must be guaranteed by an eligible guarantor institution (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions with membership in an approved Signature Guarantee Medallion Program), pursuant to SEC Rule 17Ad-15.

THE CORPORATION WILL FURNISH TO ANY STOCKHOLDER, UPON REQUEST AND WITHOUT CHARGE, A FULL STATEMENT OF THE DESIGNATIONS, RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF THE SHARES OF EACH CLASS AND SERIES AUTHORIZED TO BE ISSUED, SO FAR AS THE SAME HAVE BEEN DETERMINED, AND OF THE AUTHORITY, IF ANY, OF THE BOARD TO DIVIDE THE SHARES INTO CLASSES OR SERIES AND TO DETERMINE AND CHANGE THE RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF ANY CLASS OR SERIES. SUCH REQUEST MAY BE MADE TO THE SECRETARY OF THE CORPORATION OR TO THE TRANSFER AGENT NAMED ON THIS CERTIFICATE.

Exhibit 4.2

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY (180) DAYS FOLLOWING THE LATER OF THE EFFECTIVE DATE (DEFINED BELOW) OR THE COMMENCEMENT OF SALES OF THE OFFERING TO WHICH THIS PURCHASE WARRANT RELATES TO ANYONE OTHER THAN (I) AEGIS CAPITAL CORP. OR AN UNDERWRITER OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING, OR (II) A BONA FIDE OFFICER OR PARTNER OF AEGIS CAPITAL CORP. OR OF ANY SUCH UNDERWRITER OR SELECTED DEALER.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO [**DATE THAT IS 180 DAYS FROM THE EFFECTIVE DATE OF THE OFFERING**].

VOID AFTER 5:00 P.M., EASTERN TIME, [**DATE THAT IS FIVE YEARS FROM THE EFFECTIVE DATE OF THE OFFERING**].

WARRANT TO PURCHASE COMMON STOCK

GREENWICH LIFESCIENCES, INC.

Warrant Shares: _____[1]

Initial Exercise Date: [**DATE THAT IS 180 DAYS FROM THE EFFECTIVE DATE OF THE OFFERING**]

THIS WARRANT TO PURCHASE COMMON STOCK (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after _____, 2021 (the "Initial Exercise Date") and, in accordance with FINRA Rule 5110(f)(2)(G)(i), prior to at 5:00 p.m. (New York time) on _____, 2025 (the "Termination Date"), but not thereafter, to subscribe for and purchase from Greenwich LifeSciences, Inc., a Delaware corporation (the "Company"), up to _____[1] shares of common stock, par value $0.001 per share (the "Common Stock"), of the Company (the "Warrant Shares"), as subject to adjustment hereunder. The purchase price of one Warrant Share under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Effective Date" means the effective date of the registration statement on Form S-1 (File No. 333-238829), including any related prospectus or prospectuses, for the registration of the Company's Common Stock and the Warrant Shares under the Securities Act, that the Company has filed with the Commission.

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1 8% of the total number of shares sold in the offering, excluding shares sold in connection with exercise of the over-allotment option.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Trading Day" means a day on which the principal Trading Market located in the United States is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Underwriting Agreement" means the underwriting agreement, dated _____, 2020, by and between the Company and Aegis Capital Corp., as representatives of the underwriters set forth therein.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of a share of Common Stock for such date (or the nearest preceding date) on the OTCQB or OTCQX as applicable, (c) if Common Stock is not then listed or quoted for trading on the OTCQB or OTCQX and if prices for Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of the Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Section 2. Exercise.

a. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise Form annexed hereto. Within two (2) Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within five (5) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise Form within two (2) Business Days of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b. Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be $_____[2], subject to adjustment hereunder (the "Exercise Price"). In the event that this Warrant is exercised for cash prior to _____, 202__[3], the Exercise Price shall be $_____.[4]

c. Cashless Exercise. If at any time on or after the Initial Exercise Date, there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive the number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a "cashless exercise," the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

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2 125% of the public offering price per share of common stock in the offering.

3 Date that is six months from the Initial Exercise Date.

4 97% of 125% of the public offering price per share of common stock in the offering.

d. Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by its transfer agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through DWAC if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder, or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 and, in either case, the Warrant Shares have been sold by the Holder prior to the Warrant Share Delivery Date (as defined below), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). If the Warrant Shares can be delivered via DWAC, the transfer agent shall have received from the Company, at the expense of the Company, any legal opinions or other documentation required by it to deliver such Warrant Shares without legend (subject to receipt by the Company of reasonable back up documentation from the Holder, including with respect to affiliate status) and, if applicable and requested by the Company prior to the Warrant Share Delivery Date, the transfer agent shall have received from the Holder a confirmation of sale of the Warrant Shares (provided the requirement of the Holder to provide a confirmation as to the sale of Warrant Shares shall not be applicable to the issuance of unlegended Warrant Shares upon a cashless exercise of this Warrant if the Warrant Shares are then eligible for resale pursuant to Rule 144(b)(1)). The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price (or by cashless exercise, if permitted) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(vi) prior to the issuance of such shares, having been paid. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the second (2^{nd}) Trading Day following the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth (5^{th}) Trading Day after such liquidated damages begin to accrue) for each Trading Day after the second Trading Day following such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause its transfer agent to deliver to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise; provided, however, that the Holder shall be required to return any Warrant Shares or Common Stock subject to any such rescinded exercise notice concurrently with the return to Holder of the aggregate Exercise Price paid to the Company for such Warrant Shares and the restoration of Holder's right to acquire such Warrant Shares pursuant to this Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause its transfer agent to transmit to the Holder the Warrant Shares pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all transfer agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

viii. Signature. This Section 2 and the exercise form attached hereto set forth the totality of the procedures required of the Holder in order to exercise this Purchase Warrant. Without limiting the preceding sentences, no ink-original exercise form shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any exercise form be required in order to exercise this Purchase Warrant. No additional legal opinion, other information or instructions shall be required of the Holder to exercise this Purchase Warrant. The Company shall honor exercises of this Purchase Warrant and shall deliver Shares underlying this Purchase Warrant in accordance with the terms, conditions and time periods set forth herein.

e. Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two (2) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be [4.99]% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a. Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification. For the purposes of clarification, the Exercise Price of this Warrant will not be adjusted in the event that the Company or any subsidiary thereof, as applicable, sells or grants any option to purchase, or sell or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any Common Stock or Common Stock equivalents, at an effective price per share less than the Exercise Price then in effect.

b. [RESERVED]

c. Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d. Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend (other than cash dividends) or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of shares or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

e. Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable by holders of Common Stock as a result of such Fundamental Transaction for each share of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the Exercise Price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

f. Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g. Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly mail to the Holder a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be mailed a notice to the Holder at its last address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to provide such notice or any defect therein shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a Transferability. Pursuant to FINRA Rule 5110(g)(1), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the Effective Date or commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

i. by operation of law or by reason of reorganization of the Company;

ii. to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;

iii. if the aggregate amount of securities of the Company held by the Holder or related person do not exceed one percent (1%) of the securities being offered;

iv. that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than ten percent (10%) of the equity in the fund; or

v. the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period.

Subject to the foregoing restriction, any applicable securities laws and the conditions set forth in Section 4(d), this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b. New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c. Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d. Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Registration Rights.

a. Demand Registration.

i. Grant of Right. The Company, upon written demand (a "Demand Notice") of the Holder(s) of at least 51% of the Warrants and/or the underlying Warrant Shares, agrees to register on Form S-3 (if available) or Form S-1 (if Form S-3 is not available), on one occasion, all or any portion of the Warrant Shares underlying the Warrants (collectively, the "Registrable Securities"). On such occasion, the Company will file a registration statement with the Commission covering the Registrable Securities within sixty (60) days after receipt of a Demand Notice and use its reasonable best efforts to have the registration statement declared effective promptly thereafter, subject to compliance with review by the Commission; provided, however, that the Company shall not be required to comply with a Demand Notice if the Company has filed a registration statement with respect to which the Holder is entitled to piggyback registration rights pursuant to Section 5(b) hereof and either: (i) the Holder has elected to participate in the offering covered by such registration statement or (ii) if such registration statement relates to an underwritten primary offering of securities of the Company, until the offering covered by such registration statement has been withdrawn or until thirty (30) days after such offering is consummated. The demand for registration may be made at any time beginning on the Initial Exercise Date. The Company covenants and agrees to give written notice of its receipt of any Demand Notice by any Holder(s) to all other registered Holders of the Warrants and/or the Registrable Securities within ten (10) days after the date of the receipt of any such Demand Notice.

ii. Terms. The Company shall bear all fees and expenses attendant to the registration of the Registrable Securities pursuant to Section 5(a)(i), but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. The Company agrees to use its best efforts to cause the filing required herein to become effective promptly and to qualify or register the Registrable Securities in such States as are reasonably requested by the Holder(s); provided, however, that in no event shall the Company be required to register the Registrable Securities in a State in which such registration would cause: (i) the Company to be obligated to register or license to do business in such State or submit to general service of process in such State or (ii) the principal shareholders of the Company to be obligated to escrow their shares of capital stock of the Company. The Company shall cause any registration statement filed pursuant to the demand right granted under Section 5(a)(i) to remain effective for a period of at least twelve (12) consecutive months after the date that the Holders of the Registrable Securities covered by such registration statement are first given the opportunity to sell all of such securities. The Holders shall only use the prospectuses provided by the Company to sell the Warrant Shares covered by such registration statement, and will immediately cease to use any prospectus furnished by the Company if the Company advises the Holder that such prospectus may no longer be used due to a material misstatement or omission. Notwithstanding the provisions of this Section 5(a)(ii), the Holder shall be entitled to a demand registration under this Section 5(a)(ii) on only one (1) occasion and such demand registration right shall terminate on the fifth (5^{th}) anniversary of the Effective Date or commencement of sales of the offering pursuant to which this Warrant is being issued in accordance with FINRA Rule 5110(f)(2)(G)(iv).

b. "Piggy-Back" Registration.

i. Grant of Right. In addition to the demand right of registration described in Section 5(a) hereof, the Holder shall have the right, for a period of no more than five years from the Effective Date in accordance with FINRA Rule 5110(f)(2)(G)(v), to include the Registrable Securities as part of any other registration of securities filed by the Company (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to Form S-8 or any equivalent form); provided, however, that if, solely in connection with any primary underwritten public offering for the account of the Company, the managing underwriter(s) thereof shall, in its reasonable discretion, impose a limitation on the number of shares of Common Stock which may be included in the Registration Statement because, in such underwriter(s)' judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such Registration Statement only such limited portion of the Registrable Securities with respect to which the Holder requested inclusion hereunder as the underwriter shall reasonably permit. Any exclusion of Registrable Securities shall be made pro rata among the Holders seeking to include Registrable Securities in proportion to the number of Registrable Securities sought to be included by such Holders; provided, however, that the Company shall not exclude any Registrable Securities unless the Company has first excluded all outstanding securities, the holders of which are not entitled to inclusion of such securities in such Registration Statement or are not entitled to pro rata inclusion with the Registrable Securities.

ii. Terms. The Company shall bear all fees and expenses attendant to registering the Registrable Securities pursuant to Section 5(b)(i) hereof, but the Holders shall pay any and all underwriting commissions and the expenses of any legal counsel selected by the Holders to represent them in connection with the sale of the Registrable Securities. In the event of such a proposed registration, the Company shall furnish the then Holders of outstanding Registrable Securities with not less than fifteen (15) days written notice prior to the proposed date of filing of such registration statement. Such notice to the Holders shall continue to be given for each registration statement filed by the Company during the two (2) year period following the Initial Exercise Date until such time as all of the Registrable Securities have been sold by the Holder. The holders of the Registrable Securities shall exercise the "piggy-back" rights provided for herein by giving written notice within five (5) days of the receipt of the Company's notice of its intention to file a registration statement. Except as otherwise provided in this Warrant, there shall be no limit on the number of times the Holder may request registration under this Section 5(b)(ii); provided, however, that such registration rights shall terminate on the fifth (5^{th}) anniversary of the date of the Underwriting Agreement in accordance with FINRA Rule 5110(f)(2)(G)(v).

c. General Terms.

i. Indemnification. The Company shall indemnify the Holder(s) of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Securities Act or Section 20(a) of the Exchange Act against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Securities Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify the Underwriters contained in Section 7(a) of the Underwriting Agreement. The Holder(s) of the Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Securities Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in Section 7(a) of the Underwriting Agreement.

ii. Exercise of Warrants. Nothing contained in this Warrant shall be construed as requiring the Holder(s) to exercise their Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

iii. Documents Delivered to Holders. The Company shall deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below and to the managing underwriter, if any, copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times as any such Holder shall reasonably request.

iv. Intentionally Omitted.

v. Documents to be Delivered by Holder(s). Each of the Holder(s) participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

vi. Damages. Should the registration or the effectiveness thereof required by Sections 5(a) or 5(b) hereof be delayed by the Company or the Company otherwise fails to comply with such provisions, the Holder(s) shall, in addition to any other legal or other relief available to the Holder(s), be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

Section 6. Miscellaneous.

a. No Rights as Stockholder until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i).

b. Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c. Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

d. Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e. Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Underwriting Agreement.

f. Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g. Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Underwriting Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h. Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Underwriting Agreement.

i. Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j. Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k. Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l. Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

m. Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n. Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

GREENWICH LIFESCIENCES, INC.

By: _____

Name:
Title:

NOTICE OF EXERCISE

TO: GREENWICH LIFE SCIENCES, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant, and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please register and issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number or by physical delivery of a certificate to:

[_____]
[_____]
[_____]

(4) Accredited Investor. If the Warrant is being exercised via cash exercise, the undersigned is an "accredited investor" as defined in Regulation D promulgated under the Securities Act of 1933, as amended

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [ ] all of or [ ] shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

whose address is

.

Dated: ,

Holder's Signature: _____

Holder's Address: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

Exhibit 5.1

SheppardMullin

Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112-0015
212.653.8700 main
212.653.8701 fax
www.sheppardmullin.com

June 22, 2020

VIA ELECTRONIC MAIL
Greenwich LifeSciences, Inc.
3992 Bluebonnet Dr, Building 14
Stafford, TX 77477

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We are acting as counsel to Greenwich LifeSciences, Inc. (the "Company") in connection with its registration statement on Form S-1 (File No. 333-238829), as amended (the "Registration, Statement") filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act"), relating to (i) the proposed public offering of 1,150,000 shares (the "Shares") of common stock of the Company, par value $0.001 per share (the "Common Stock"), including Shares issuable upon exercise of an option granted by the Company, (ii) the resale of 1,685,394 shares (the "Resale Shares") of the Company's Common Stock held by certain selling stockholders named therein and (iii) warrants to be issued by the Company to the underwriters of the Company named in the Registration Statement to purchase up to 8% of the number of shares of Common Stock (the "Underwriters' Warrants") upon the closing of the public offering pursuant to which the Registration Statement relate. The Shares will be sold by the Company pursuant to an underwriting agreement to be entered into by and between the Company and Aegis Capital Corp. as the representative of the several underwriters to be named therein (the "Agreement"). This opinion letter is furnished to you at your request to enable you to fulfill the requirements of Item 601(b)(5) of Regulation S-K in connection with the Registration Statement.

In connection with this opinion, we have reviewed and relied upon the following:

- the Registration Statement and the related prospectus included therein;
- the form of Agreement;
- the form of the Underwriters' Warrants;
- The Amended and Restated Certificate of Incorporation of the Company, as amended and in effect on the date hereof;
- The Amended and Restated Bylaws of the Company in effect on the date hereof;
- the resolutions of the Board of Directors of the Company authorizing/ratifying the execution and delivery of the Agreement, the issuance and sale of the Shares, the issuance of the Underwriters' Warrants, the issuance of the Resale Shares, the preparation and filing of the Registration Statement, and other actions with regard thereto; and
- such other documents, records, certificates, memoranda and other instruments as we deem necessary as a basis for this opinion.

In our examination, we have assumed the genuineness of all signatures, including endorsements, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photocopy, and the authenticity of the originals of such copies. As to any facts relevant to the opinions stated herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and others and of public officials.

Based upon, subject to and limited by the foregoing, we are of the opinion that:

1. Following (i) execution and delivery by the Company of the Agreement, (ii) effectiveness of the Registration Statement, (iii) issuance of the Shares pursuant to the terms of the Agreement, and (iv) receipt by the Company of the consideration for the Shares specified in the resolutions, the Shares will be duly authorized for issuance and, when issued, delivered and paid for in accordance with the terms of the Agreement, will be validly issued, fully paid and non-assessable.

SheppardMullin

Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112-0015
212.653.8700 main
212.653.8701 fax
www.sheppardmullin.com

2. The Resale Shares have been duly authorized by all requisite corporate action on the part of the Company under the General Corporation Law of the State of Delaware (the "DGCL") and are validly issued, fully paid and non-assessable.

3. The Underwriters' Warrants have been duly authorized by all requisite corporate action on the part of the Company under the DGCL and, provided that the Underwriters' Warrants have been duly executed and delivered by the Company and duly delivered to the purchasers thereof against payment therefor, the Underwriters' Warrants, when issued and sold as contemplated in the Registration Statement will be valid and legally binding obligations of the Company, enforceable against the Company in accordance with their terms, except as enforcement thereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditors' rights generally and by general equitable principles (regardless of whether such enforceability is considered in a proceeding at law or in equity).

4. The shares of Common Stock issuable upon exercise of the Underwriters' Warrants (the "Warrant Shares" and together with the Underwriters' Warrants, the Shares and the Resale Shares, the "Securities") have been duly authorized by all requisite corporate action on the part of the Company under the DGCL and, when the Warrant Shares are delivered to and paid for in accordance with the terms of the Underwriters' Warrants and when evidence of the issuance thereof is duly recorded in the Company's books and records, the Warrant Shares will be validly issued, fully paid and non-assessable.

We also hereby consent to the reference to our firm under the caption "Legal Matters" in the prospectus which forms part of the Registration Statement. In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Act, the rules and regulations of the Commission promulgated thereunder or Item 509 of Regulation S-K.

We express no opinion as to matters governed by any laws other than the DGCL. No opinion is expressed herein with respect to the qualification of the Securities under the securities or blue sky laws of any state or any foreign jurisdiction.

This opinion letter is rendered as of the date first written above and we disclaim any obligation to advise you of facts, circumstances, events or developments which hereafter may be brought to our attention and which may alter, affect or modify the opinion expressed herein. Our opinion is expressly limited to the matters set forth above and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company or the Securities, or any other agreements or transactions that may be related thereto or contemplated thereby. We are expressing no opinion as to any obligations that parties other than the Company may have under or in respect of the Securities or as to the effect that their performance of such obligations may have upon any of the matters referred to above. No opinion may be implied or inferred beyond the opinion expressly stated above.

Very truly yours,

/s/ Sheppard, Mullin, Richter & Hampton LLP

SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

Exhibit 10.3

EXCLUSIVE LICENSE AGREEMENT

BETWEEN

THE HENRY M. JACKSON FOUNDATION FOR THE
ADVANCEMENT OF MILITARY MEDICINE, INC.

AND

NORWELL, INC.

THIS EXCLUSIVE LICENSE AGREEMENT is entered into as of the 24th day of April, 2009 (the "Effective Date"), by and between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a tax-exempt corporation organized under the laws of the State of Maryland and having its principal offices at 1401 Rockville Pike, Suite 600, Rockville, Maryland 20852 (the "Foundation") and Norwell, Inc., a corporation organized under the laws of the State of Delaware and having its principal offices at 415 Jackson Hill, Houston, Texas ("Licensee"). The Foundation and Licensee sometimes are referred to collectively herein as the "Parties" or individually as a "Party."

WHEREAS the Foundation and the Uniformed Services University of the Health Sciences, an institution of higher learning within the Department of Defense, an agency of the United States Government, located at 4301 Jones Bridge Road, Bethesda, Maryland 20814 ("USU") have agreed to collaborate in the development and commercialization of inventions, patents, trade secrets, and other intellectual property rights;

WHEREAS, the Foundation and USU are committed to the policy that ideas or creative works produced at the Foundation and USU should be used for the greatest possible public benefit and that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest;

WHEREAS the Foundation, by assignment from Foundation employees and by assignment from USU, is an owner of certain Patent Rights (as hereinafter defined) and has the right to grant licenses of said Patent Rights, subject to a royalty-free, nonexclusive license heretofore granted to or retained by the United States Government;

WHEREAS Licensee is experienced in the development, production, manufacture, marketing, and sale of products similar to the Licensed Products and the use of processes similar to the Licensed Processes (both as hereinafter defined) and that it shall commit itself to a commercially practicable program of exploiting the Patent Rights so that public utilization shall result therefrom; and

WHEREAS Licensee desires to obtain from the Foundation, and the Foundation agrees to grant to Licensee, a license upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth in this Agreement, the Parties, intending to be legally bound, agree as follows:

ARTICLE I
DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

1.1 “Affiliate” means, with respect to any Person, any other Person that directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person. For purposes of this definition, the term “controls” (including its correlative meanings “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

1.2 “Agreement” means this Agreement, including all Appendices hereto, as the same may be amended from time to time in accordance with the terms hereof.

1.3 “Business Day” means any day other than a Saturday, a Sunday, or a day on which banking institutions in Montgomery County, Maryland are closed.

1.4 “Confidential Information” means information, disclosed by one Party to the other Party, that is treated as proprietary or confidential by the disclosing Party and, at the time of disclosure, that is marked “proprietary” or “confidential” or that bears a marking or legend of like import restricting its use, copying, or dissemination or that is identified as being confidential in a letter or other written communication sent to the receiving Party prior to or contemporaneously with disclosure to the receiving Party. Any such information that is in another form when disclosed, such as oral or visual, shall be treated as Confidential Information only if and to the extent the disclosing Party informs the receiving Party of the proprietary or confidential nature of the information prior to or at the time of the disclosure, and thereafter creates a written record of the disclosure (marked in accordance with this Agreement) and delivers the written record to the receiving Party promptly, but in no event more than thirty (30) days after the original disclosure to the receiving Party. Confidential Information does not include any information that (i) was known to the receiving party without a duty of confidentiality before receipt from the disclosing party as evidenced by written records made prior to such receipt or disclosure (when such prior knowledge did not become known to such receiving party through disclosure by a third party known to the receiving party to be subject to an obligation to maintain the confidentiality thereof); (ii) is or becomes a matter of public knowledge through no fault of the receiving party or any of its agents; (iii) is rightfully received by the receiving party from a third party without a duty of confidentiality; or (iv) is independently developed by the receiving party as evidenced by written records of the receiving party.

1.5 “Field” means: (a) all fields of use with respect to Patent 1; and (b) use of the HER family peptide GP2 in combination with Herceptin® and only in the field of human therapeutics with respect to Patent 2 (no licensed use is granted in connection with any other peptides). Patent 1 and Patent 2 are defined in Appendix A.

1.6 “Licensed Process” means any process that is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights.

1.7 “Licensed Product” means any product or part thereof that: (a) is covered in whole or in part by an unexpired issued or pending claim contained in the Patent Rights, or (b) is manufactured by using or is employed to practice a Licensed Process.

1.8 “Marketing Approval” means the approval or authorization required for the marketing of Licensed Product or Licensed Process in the United States, the European Union, or other country within the Territory, such as the issuance of an approval action by the United States Food and Drug Administration (“FDA”) on an NDA in the United States, or the issuance of its equivalent by the European Medicines Agency in the European Union.

1.9 “NDA” means a New Drug Application or Biologics License Application filed with the FDA for Marketing Approval of a Licensed Product or Licensed Process, or an equivalent application filed with any equivalent agency or governmental authority outside the United States.

1.10 “Net Sales” means all amounts (including the fair market value of any non-cash consideration) billed, invoiced, or received (whichever first occurs) by Licensee or any sublicensee(s) for sales, leases, or other transfers of any Licensed Products or Licensed Processes, less the sum of the following:

(a) customary trade, quantity, or cash discounts actually allowed and taken;

(b) amounts repaid or credited by reason of rejection or return;

(c) to the extent separately stated on purchase orders, invoices, or other documents of sale, sales taxes, tariff duties, and use taxes directly imposed on sale, transportation, delivery, or use and paid by or on behalf of Licensee or sublicensees; and

(d) reasonable charges for delivery or transportation provided by non-affiliated third parties, if separately stated and prepaid or actually allowed.

No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by and on the payroll of Licensee or sublicensees, or for the cost of collections.

1.11 “Non-commercial Research Purposes” means use of Patent Rights for academic research or other not-for-profit scholarly purposes that are undertaken at a non-profit or governmental institution that does not use the Patent Rights in the production or manufacture of products for sale or the performance of services for a fee.

1.12 “Non-royalty Sublicense Income” means all sublicense issue fees, sublicense maintenance fees, sublicense milestone payments, and similar non-royalty payments made by sublicensees to Licensee on account of sublicenses pursuant to this Agreement.

1.13 “Patent Rights” means any or all of the following intellectual property to the extent owned or controlled by the Foundation:

(a) the United States and foreign patents and patent applications listed in Appendix A and all divisions and continuations of such applications;

(b) United States and foreign patents issued from the applications listed in Appendix A or from divisionals or continuations of such applications;

(c) claims of United States and foreign continuation-in-part applications, and all divisions and continuations of such continuation-in-part applications, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the United States or foreign patent applications listed in Appendix A;

(d) claims of all foreign and United States counterpart patent applications to (a), (b), or (c) above, and of the resulting patents, to the extent that the claims are directed to subject matter specifically described in the patents or patent applications described in (a), (b), or (c) above; and

(e) any reissues, renewals, reexamination certificates, extensions, or supplementary protection certificates of patents described in (a), (b), (c), or (d) above.

Patent Rights shall not include (c), (d), or (e) above to the extent that the claims are directed to new matter that is not the subject matter described in (a) above.

1.14 “Person” means any individual, corporation, limited liability company, general or limited partnership, joint venture, association, joint stock company, trust, unincorporated business or organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary, or other capacity.

1.15 “Phase III Clinical Trial” means: (a) that portion of the drug development and review process in which expanded clinical trials are conducted to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of an investigational new drug, as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21 or any future revisions or substitutes therefore; or (b) a similar clinical trial in any national jurisdiction other than the United States. Commencement of a Phase III Clinical Trial shall be deemed to occur upon the administration of Licensed Product (or Licensed Process) or placebo to the first patient enrolled in the Phase III Clinical Trial.

1.16 “Territory” means Worldwide.

1.17 “Valid Claim” means a claim of: any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal; or (b) any pending patent application that has not been cancelled, withdrawn, or abandoned.

ARTICLE II
GRANT OF RIGHTS

2.1 The Foundation hereby grants to Licensee and Licensee accepts, subject to the terms and conditions hereof, in the Territory and for the Field, an exclusive license to practice under the Patent Rights and, to the extent not prohibited by other patents, and to make, have made, use, have used, sell, have sold, export and import Licensed Products and Licensed Processes, until the end of the last-expiring term for which any of the Patent Rights are granted, unless this Agreement shall be sooner terminated in accordance with the terms hereof.

2.2 In order to establish a period of commercial exclusivity for Licensee, the Foundation agrees that it will not grant, in the Territory for the Field, any other license to make, have made, use, have used, sell, have sold, export or import Licensed Products or to practice the Licensed Processes, except as required by the Foundation’s obligations related to Section 2.4(a) or as permitted in Section 2.4(b), during the period of time commencing with the Effective Date and ending with the first to occur of:

(a) the expiration of all Patent Rights;

(b) a court or tribunal, in a final decision not subject to further appeal, declaring invalid or unenforceable all claims in the Patent Rights;

(c) the abandonment of all claims in the Patent Rights; or

(c) the termination of this Agreement or the termination or expiration of the exclusivity of Licensee’s license in accordance with Article IX.

2.3 Subject to the Foundation’s prior approval, which approval shall not be unreasonably withheld, Licensee shall have the right to grant sublicenses hereunder via written sublicense agreements. The license granted to Licensee hereunder does not extend to any Affiliate of Licensee unless and until such Affiliate enters into a written sublicense agreement with Licensee that is consistent with the requirements hereof and the Foundation approves the written sublicense agreement between the Affiliate and Licensees.

(a) In all sublicenses granted hereunder, Licensee shall provide that the sublicense is subject and subordinate to all terms and conditions of this Agreement, except: (i) the sublicensee may not grant any sublicenses except with the Foundation's prior express written approval, and (ii) the rate of royalty on Net Sales paid by the sublicensee to Licensee may exceed the rate set forth in this Agreement. Licensee shall attach a copy of this Agreement to any sublicense agreement and shall provide a complete copy of the sublicense agreement to the Foundation promptly after signing by the parties thereto.

(b) Licensee may not receive from any sublicensee anything of value in lieu of cash payments in consideration for any sublicense under this Agreement, without the Foundation's prior express written approval.

(c) Sublicenses may extend past the expiration date of the exclusive period but any exclusivity of such sublicenses shall expire upon the termination or expiration of Licensee's exclusivity. Upon any termination of this Agreement, sublicensees' rights shall also terminate, subject to Section 10.3 hereof.

2.4 The granting and exercise of this license is subject to the following conditions:

(a) The U.S. Government retains a nonexclusive, nontransferable, irrevocable, world-wide, paid-up license to practice all invention(s) covered by the Patent Rights and to have such invention(s) practiced by or on behalf of the U.S. Government.

(b) The Foundation and the USU reserve the rights to make and use, and grant to others non-exclusive licenses to make and use for Non-commercial Research Purposes the subject matter described and claimed in Patent Rights.

(c) Licensee shall cause any Licensed Product produced for use or sale in the United States to be manufactured substantially in the United States unless a waiver is granted in accordance with 35 U.S.C § 204.

2.5 The license granted hereunder shall not be construed to confer any rights upon Licensee (or sublicensees, if any) by implication, estoppel, or otherwise as to any technology not included in Patent Rights as defined herein.

ARTICLE III
ROYALTIES, MILESTONE PAYMENTS, AND EQUITY

3.1 Licensee shall pay to the Foundation a non-creditable, non-refundable license issue royalty in the sum of Fifty Thousand dollars ($50,000.00) upon execution of this Agreement.

3.2 No later than thirty (30) days after the close of Licensee's Series A financing, Licensee shall transfer to Foundation an equity position in Licensee equal to Two Hundred and Fifty Thousand dollars ($250,000.00) or Ten percent (10%) of the outstanding shares of Licensee, whichever is greater, based on the pre-money valuation of the Series A financing.

3.3 Licensee shall pay to the Foundation semi-annually, within sixty (60) days after each calendar half year ending June 30 and December 31, the greater of: (i) a semi-annual minimum royalty of Fifty Thousand dollars ($50,000.00); or (ii) a running royalty of Five percent (5%) of Net Sales by Licensee and sublicensees in a given jurisdiction covered by at least one Valid Claim existing in such jurisdiction and Two and One-Half percent (2.5%) of Net Sales by Licensee and sublicensees in a given jurisdiction not covered by any Valid Claim existing in such jurisdiction. In the case of sublicenses, Licensee shall also pay to the Foundation a royalty of Fifteen percent (15%) of Non-royalty Sublicense Income.

(a) If the license pursuant to this Agreement is converted to a non-exclusive one and if other non-exclusive licenses in the same field and territory are granted, after such conversion the above royalty rates shall not exceed the royalty rate to be paid by other licensees in the same field and territory during the term of the non-exclusive license.

(b) On sales of Licensed Products or Licensed Processes between Licensee and its sublicensees for resale, the royalty shall be paid only on the Net Sales of the sublicensees and not on the Net Sales by Licensee to its sublicensees for resale.

3.4 No later than January 1 of each calendar year after the Effective Date of this Agreement, Licensee shall pay to the Foundation the following non-refundable license maintenance royalties. Such maintenance royalty payments may be credited against running royalties due (pursuant to Section 3.2) for that calendar year only, and Royalty Reports (pursuant to Section 5.3) shall reflect such a credit. Such payments shall not be credited against any milestone payments nor against royalties due for any other calendar year.

Patent 1:		
January 1, 2010	$	12,500.00
January 1, 2011	$	37,500.00
January 1 of each year thereafter until the filing of an NDA for a Licensed Product or Licensed Process utilizing Patent 1	$	25,000.00

Patent 2:		
January 1, 2010	$	12,500.00
January 1, 2011	$	37,500.00
January 1 of each year thereafter until the filing of an NDA for a Licensed Product or Licensed Process utilizing Patent 2	$	25,000.00

3.5 Licensee shall pay to the Foundation the following milestone payment(s) within thirty (30) days after the associated milestone occurs (in each instance):

Licensed Product or Licensed Process Utilizing Patent 1:		
Commencement of Phase III Clinical Trial	$	100,000.00
Filing of an NDA	$	500,000.00
Marketing Approval	$	750,000.00
First commercial sale	$	1,000,000.00

Licensed Product or Licensed Process Utilizing Patent 2:		
Commencement of Phase III Clinical Trial	$	100,000.00
Filing of an NDA	$	500,000.00
Marketing Approval	$	750,000.00
First commercial sale	$	1,000,000.00

3.6 Licensee agrees to pay Foundation Three Million dollars ($3,000,000.00) in support of the GP2 breast cancer vaccine Phase II clinical trial (hereinafter "Clinical Trial Financial Support"). Licensee acknowledges that the GP2 breast cancer vaccine Phase II clinical trial has already commenced and that the Parties intend Licensee's Clinical Trial Financial Support to cover past, ongoing, and future expenses associated with the GP2 breast cancer vaccine Phase II clinical trial. Beginning no later than January, 1, 2010 and continuing on a quarterly basis thereafter, Licensee shall pay Foundation Two Hundred Fifty Thousand dollars ($250,000.00) on the first day of each quarter until Licensee's Clinical Trial Financial Support obligation is fulfilled. In the event the GP2 breast cancer vaccine Phase II clinical trial is terminated prior to completion of the trial, Licensee's Clinical Trial Financial Support obligation will be adjusted proportionally to correspond to the reduced number of patients enrolled.

3.7 All payments due hereunder shall be paid in full, without deduction for any taxes or other fees imposed by any government or any transfer, collection, or similar charges; any such tax, fee, or charge shall be paid by Licensee.

3.8 Royalty payments shall be paid by check or by wire transfer in United States dollars in Rockville, Maryland, or at such other place and manner as the Foundation may designate in writing consistent with the laws and regulations controlling in any foreign country. If any currency conversion is required in connection with any payments due hereunder, such conversion shall be made by using the exchange rate existing in the United States as reported in the Wall Street Journal on the last Business Day of the calendar half-year reporting period to which such payments relate.

3.9 No multiple royalty shall be due to the Foundation because any Licensed Product, its manufacture, use, lease, or sale, are or shall be covered by more than one Patent Rights patent application or Patent Rights patent licensed hereunder.

ARTICLE IV
DUE DILIGENCE

4.1 Licensee shall use its best efforts to bring one or more of the Licensed Products and Licensed Processes to market, in the Territory for the Field, through a commercially practicable program for exploitation of the Patent Rights and to continue such development and marketing efforts for such Licensed Products and Licensed Processes throughout the life of this Agreement. Thereafter, until the expiration of this Agreement, Licensee shall endeavor to keep Licensed Products and Licensed Processes continuously available to the public in the Territory for the Field.

4.2 Within twenty-four (24) months of the Effective Date, Licensee shall raise at least Three Million dollars ($3,000,000.00) in funding (whether by debt, equity, or grant) and provide evidence of same to Foundation.

ARTICLE V
REPORTING

5.1 No later than sixty (60) days after December 31 of each calendar year, Licensee shall provide to the Foundation a written annual Progress Report describing progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing, and sales during the most recent twelve (12) month period ending December 31 and plans for the forthcoming year. The Progress Report shall describe the status of Licensee's efforts to develop and commercialize Licensed Product(s) or Licensed Process(es) in sufficient detail to enable the Foundation to reasonably determine whether anticipated performance and payment milestones have been met and to provide assurance that Licensee is developing Licensed Product(s) or Licensed Process(es). If multiple technologies are covered by the license granted hereunder, the Progress Report shall provide the information set forth above for each technology. Licensee shall also provide any reasonable additional data the Foundation requires to evaluate Licensee's performance.

5.2 Licensee shall report to the Foundation the date of first sale of Licensed Products (or use or sale of Licensed Processes) in each country within thirty (30) days of occurrence.

5.3 Royalty Reports.

(a) Licensee shall submit to the Foundation, within sixty (60) days after each calendar half year ending June 30 and December 31, a Royalty Report setting forth for such half year at least the following information:

(i) the number of Licensed Products sold by Licensee and all sublicensees in each country;

(ii) total dollar amount of billings, invoices, and receipts for Licensed Products sold by Licensee and all sublicensees in each country (together with an accounting for currency conversions, if any);

(iii) an accounting for all Licensed Processes used or sold by Licensee and all sublicensees in each country;

(iv) deductions applicable to determine the Net Sales;

(v) the amount of Non-royalty Sublicense Income received by Licensee; and

(vi) the amount of royalty due to the Foundation for the reporting period or, if no royalties are due for any reporting period, the statement that no royalties are due.

Such Royalty Report shall be certified as correct by an officer of Licensee and shall include a detailed listing of all deductions from royalties.

(b) Contemporaneous with submission of each Royalty Report, Licensee shall pay to the Foundation the amount of royalty due with respect to such half year. If multiple technologies are covered by the license granted hereunder, Licensee shall specify which Patent Rights are utilized for each Licensed Product and Licensed Process included in the Royalty Report.

(c) Late payments shall be subject to a charge of one and one-half percent (1-1/2%) per month, or $250, whichever is greater.

5.4 In the event of acquisition, merger, change of corporate name, or change of make-up, organization, or identity, Licensee shall notify the Foundation in writing within thirty (30) days of such event.

5.5 If Licensee or any Affiliate or sublicensee (or optionee) does not qualify or ceases to qualify as a “small entity” as provided by the United States Patent and Trademark Office, Licensee must notify the Foundation immediately.

5.6 Foundation shall make available to the Licensee all preclinical, manufacturing, and clinical data and information in its possession related to the Patent Rights licensed hereunder.

ARTICLE VI
RECORD KEEPING

6.1 Licensee shall keep, and shall require its sublicensees to keep, accurate records (together with supporting documentation) of Licensed Products and Licensed Processes made, used or sold under this Agreement, appropriate to determine the amount of royalties due to the Foundation hereunder. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate. They shall be available during normal business hours for examination by an accountant selected by the Foundation, for the sole purpose of verifying reports and payments hereunder. In conducting examinations pursuant to this section, the Foundation's accountant shall have access to all records that the Foundation reasonably believes to be relevant to the calculation of royalties under Article III.

6.2 The Foundation's accountant shall not disclose to the Foundation any information other than information relating to the accuracy of reports and payments made hereunder. In cases of inaccurate reports and payment, Licensee shall promptly pay the Foundation any additional sum that would have been payable to the Foundation had the Licensee reported correctly, plus interest on said sum at the rate of one and one half per cent (1 1/2%) per month.

6.3 Such examination by the Foundation's accountant shall be at the Foundation's expense, except that if such examination shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then Licensee shall pay the Foundation the cost of such examination (as well as any additional sum that would have been payable to the Foundation had the Licensee reported correctly, plus interest on said sum at the rate of one and one half per cent (1 1/2%) per month).

ARTICLE VII
DOMESTIC AND FOREIGN PATENT FILING AND MAINTENANCE

7.1 The Foundation, in its sole discretion, shall be responsible for the preparation, filing, prosecution, and maintenance of any and all patent applications and patents included in Patent Rights. The Foundation shall consult with Licensee as to the preparation, filing, prosecution and maintenance of such patent applications and patents and shall furnish to Licensee copies of documents relevant to any such preparation, filing, prosecution, or maintenance.

7.2 Licensee shall reimburse the Foundation for all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 1 ("Patent 1 Patent Expenses").

(a) For Patent 1 Patent Expenses incurred prior to the execution of this Agreement, Licensee shall reimburse Foundation according to the following schedule:

Due upon execution of Agreement	25%
Due upon one-year anniversary of Effective Date	25%
Due upon two-year anniversary of Effective Date	50%

(b) Notwithstanding the reimbursement schedule in 7.2(a), upon Licensee raising Three Million Dollars ($3,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 1 Patent Expenses the Foundation has incurred prior to the execution of this Agreement.

(c) Licensee shall reimburse the Foundation for all Patent 1 Patent Expenses incurred after the execution of this Agreement within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late payment of these invoices shall be subject to interest charges of one and one-half percent (1 1/2%) per month.

7.3 Licensee shall reimburse the Foundation for fifty percent (50%) of all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 2 ("Patent 2 Patent Expenses").

(a) For Patent 2 Patent Expenses incurred prior to the execution of this Agreement, Licensee shall reimburse Foundation according to the following schedule:

Due upon execution of Agreement	25%
Due upon one-year anniversary of Effective Date	25%
Due upon two-year anniversary of Effective Date	50%

(b) Notwithstanding the reimbursement schedule in 7.3(a), upon Licensee raising Three Million Dollars ($3,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 2 Patent Expenses the Foundation has incurred prior to the execution of this Agreement.

(c) Licensee shall reimburse the Foundation for Patent 2 Patent Expenses incurred after the execution of this Agreement within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late payment of these invoices shall be subject to interest charges of one and one-half percent (1 1/2%) per month.

7.4 The Foundation and Licensee shall cooperate fully in the preparation, filing, prosecution and maintenance of Patent Rights and of all patents and patent applications licensed to Licensee hereunder, executing all papers and instruments or requiring employees or agents to execute such papers and instruments so as to enable the Foundation to apply for, to prosecute, and to maintain patent applications and patents in the Foundation's name in any country. Each Party shall provide to the other prompt notice as to all matters that come to its attention and that may affect the preparation, filing, prosecution, or maintenance of any such patent applications or patents.

7.5 Licensee may elect to surrender its license to the Patent Rights in any country upon sixty (60) days written notice to the Foundation. Such notice shall not relieve Licensee from responsibility to reimburse the Foundation for patent-related expenses incurred prior to the expiration of the (60)-day notice period (or such longer period specified in Licensee's notice).

ARTICLE VIII
INFRINGEMENT

8.1 With respect to any Patent Rights that are exclusively licensed to Licensee pursuant to this Agreement, Licensee shall have the right, within the Territory, to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action. The Foundation agrees to notify Licensee promptly of each infringement of such patents of which the Foundation is or becomes aware. Before Licensee commences an action with respect to any infringement of such patents, Licensee shall give careful consideration to the views of the Foundation and to potential effects on the public interest in making its decision whether or not to sue.

(a) If Licensee elects to commence an action as described above, Foundation may, to the extent permitted by law, elect to join as a party in that action. Regardless of whether the Foundation elects to join as a party, the Foundation shall cooperate fully with Licensee in connection with any such action.

(b) If the Foundation elects to join as a party pursuant to subsection (a), the Foundation shall jointly control the action with Licensee.

(c) Licensee shall reimburse the Foundation for any costs the Foundation incurs, including reasonable attorneys' fees, as part of an action brought by Licensee, irrespective of whether the Foundation becomes a co-plaintiff.

8.2 If Licensee elects to commence an action as described above, Licensee may deduct from its royalty payments to the Foundation with respect to the patent(s) subject to suit an amount not exceeding fifty percent (50%) of Licensee's expenses and costs of such action, including reasonable attorneys' fees; provided, however, that such reduction shall not exceed fifty percent (50%) of the total royalty due to the Foundation with respect to the patent(s) subject to suit for each calendar year. If such fifty percent (50%) of Licensee's expenses and costs exceeds the amount of royalties deducted by Licensee for any calendar year, Licensee may to that extent reduce the royalties due to the Foundation from Licensee in succeeding calendar years, but never by more than fifty percent (50%) of the total royalty due in any one year with respect to the patent(s) subject to suit.

8.3 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of the Foundation, which consent shall not be unreasonably withheld.

8.4 Recoveries or reimbursements from actions commenced pursuant to this Article shall first be applied to reimburse Licensee and the Foundation for litigation costs not paid from royalties and then to reimburse the Foundation for royalties deducted by Licensee pursuant to Section 8.2. Licensee and the Foundation shall share any remaining recoveries or reimbursements equally.

8.5 If Licensee elects not to exercise its right to prosecute an infringement of the Patent Rights pursuant to this Article, the Foundation may do so at its own expense, controlling such action and retaining all recoveries therefrom. Licensee shall cooperate fully with the Foundation in connection with any such action.

8.6 Without limiting the generality of Section 8.5, the Foundation may, at its election and by notice to Licensee, establish a time limit of ninety (90) days for Licensee to decide whether to prosecute any infringement of which the Foundation is or becomes aware. If, by the end of such ninety (90)-day period, Licensee has not commenced such an action, the Foundation may prosecute such an infringement at its own expense, controlling such action and retaining all recoveries therefrom. With respect to any such infringement action prosecuted by the Foundation in good faith, Licensee shall pay over to Foundation any payments (whether or not designated as "royalties") made by the alleged infringer to Licensee under any existing or future sublicense authorizing Licensed Products or Licensed Processes, up to the amount of the Foundation's unreimbursed litigation expenses (including, but not limited to, reasonable attorneys' fees).

8.7 If a declaratory judgment action is brought naming Licensee as a defendant and alleging invalidity of any of the Patent Rights, the Foundation may elect to take over the sole defense of the action at its own expense. Licensee shall cooperate fully with the Foundation in connection with any such action.

8.8 During the exclusive period of the Licensee's license hereunder, Licensee shall have the sole right, in accordance with the terms and conditions hereof, to sublicense any alleged infringer within the Territory for the Field. Any upfront fees paid in connection with such sublicense shall be shared equally between Licensee and the Foundation; other royalties shall be treated in accordance with Article III.

ARTICLE IX
NEW INVENTIONS

9.1 "New Invention(s)" means any invention, discovery, or improvement of a Party or Parties conceived or first actually reduced to practice in the course of carrying out this Agreement that is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Act (7 U.S.C. § 2321 et seq).

9.2 In the event of a New Invention, inventorship shall be determined in accordance with the patent laws of the United States of America. All New Inventions conceived or first actually reduced to practice solely by an employee of a Party shall belong to the employee (or to the employee's employer if the employee and the employer have so agreed). Two or more Parties shall jointly own a New Invention if each of such Parties employed at least one inventor thereof at the time of its conception or first actual reduction to practice, provided that each Party has acquired the interest of its respective employee(s) in the New Invention. Each Party shall cooperate with the other Party(ies) to obtain inventor signatures on patent applications, assignments, and other documents required to secure the Party(ies) rights in New Inventions. Each Party shall have the primary responsibility for filing patent or other intellectual property applications on the New Inventions of its own employee(s) in a timely manner, at its own expense, and after consultation with the other Parties. Notwithstanding the foregoing, by mutual agreement, the Parties may identify which Party shall file a patent application on any New Invention. The Parties will consult and mutually determine a filing strategy for jointly owned New Inventions.

9.3 For New Inventions solely owned by Licensee, Licensee grants to the U.S. Government and Foundation a nonexclusive, nontransferable, irrevocable, world-wide, paid-up license to practice the New Invention or have the New Invention practiced throughout the world by or on behalf of the U.S. Government or the Foundation for research or other Government purposes.

9.4 The Parties intend that this Agreement qualify as a joint research agreement for the purposes of the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c) (hereinafter "CREATE Act"). However, in the event of any New Invention, the Parties agree not to invoke the CREATE Act without the prior express written consent of the other Party.

ARTICLE X
TERMINATION OF AGREEMENT

10.1 This Agreement, unless terminated as provided herein, shall remain in effect until the last patent or patent application in Patent Rights has expired or been abandoned.

10.2 The Foundation may terminate this Agreement in the circumstances set forth in this Section, and any such termination shall be effective immediately upon the Foundation giving written notice to Licensee of any of the following:

(a) if Licensee does not make any payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 5.3(c)) within thirty (30) days after the receipt of notice in writing of such non-payment by the Foundation;

(b) if Licensee defaults in its obligations under Sections 11.4(c), 11.4(d), and 11.4(e) to procure and maintain insurance;

(c) at any time after two years from the Effective Date of this Agreement, the Foundation may, in its sole discretion, either terminate this Agreement and the license granted hereunder or render this license non-exclusive if, in the Foundation's reasonable judgment, the Progress Reports furnished by Licensee do not demonstrate that Licensee has:

(i) either (A) put the licensed subject matter into commercial use in the Territory hereby licensed, directly or through a sublicense, and is keeping the licensed subject matter continuously available to the public, or (B) has been and continues to be engaged in research, development, manufacturing, marketing or sublicensing activity appropriate to achieving the purposes set forth in Section 4.1; and

(ii) met all relevant performance milestone(s) for the period covered by any Progress Report and all preceding Progress Reports;

(d) if Licensee: is unable to pay its debts as such debts become due; makes a general assignment for the benefit of creditors; has a petition in bankruptcy or a suit seeking reorganization, liquidation, dissolution, or similar relief filed against it; or files or permits the filing of any petition or answer seeking to adjudicate itself bankrupt or insolvent, or seeking for itself any liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of Licensee or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking or consenting to the appointment of a trustee, custodian, receiver, liquidator or other similar official for Licensee or for any substantial part of its property; or takes any corporate action to authorize any of the foregoing actions;

(e) if Licensee fails to raise at least Three Million dollars ($3,000,000.00) in funding (whether by debt, equity, or grant) within twenty-four (24) months of the Effective Date in accordance with Section 4.2 and provide evidence of same to the Foundation within thirty (30) days thereafter.

(f) if an examination by Foundation's accountant pursuant to Article VI shows an underreporting or underpayment by Licensee in excess of fifteen percent (15%) for any twelve (12) month period.

(g) if Licensee is convicted of a felony relating to the manufacture, use, or sale of any Licensed Product or Licensed Process, or has made a false statement of, or willfully omitted, a material fact in the annual development plan, progress report, or any other report required by this Agreement; or

(h) except as provided in subsections (a), (b), (c), (d), (e), (f) and (g) above, if Licensee defaults in the performance of any obligations under this Agreement and the default has not been remedied within ninety (90) days after the date of notice in writing of such default by the Foundation.

10.3 Licensee shall provide, in all sublicenses granted by it under this Agreement, that Licensee's interest in such sublicenses shall at the Foundation's option terminate or be assigned to the Foundation upon termination of this Agreement.

10.4 Licensee may terminate this Agreement by giving ninety (90) days advance written notice of termination to the Foundation.

10.5 Upon termination, Licensee shall pay Foundation the balance of its remaining Clinical Trial Financial Support obligation in proportion to the number of patients enrolled as of the date of termination.

10.6 Upon termination, Licensee shall submit a final Royalty Report to the Foundation and any royalty payments, including royalty payments on any and all future sales of Licensed Products made but not yet sold at the time of termination, and unreimbursed patent expenses invoiced by the Foundation shall become immediately payable.

10.7 Upon termination, Licensee shall promptly provide to Foundation all data, including all pre-clinical data, clinical data, manufacturing data, and marketing data, derived during development of Licensed Products and Licensed Processes. Licensee shall also provide to Foundation copies of all FDA submissions and correspondence related to Licensed Products and Licensed Processes.

10.8 Articles I and VI and Sections 2.4, 5.3, 7.2, 8.3, 8.4, 9.1 through 9.4 inclusive, 10.4, 10.5, 10.6, 10.7, 10.8, 11.1 through 11.8 inclusive, 11.10, 11.11, and11.13 through 11.19 inclusive shall survive any expiration or termination of this Agreement indefinitely. Additionally, any rights or remedies arising out of a breach or violation of any terms of this Agreement will survive any expiration or termination of this Agreement. The expiration or termination of this Agreement shall not discharge either Party from any obligation that it owes to the other Party by reason of any loss, cost, damage, expense, liability, or contractual duty that occurs or arises (or the circumstances, events, or basis of which occurs or arises) prior to such expiration or termination, and shall not affect the right of either Party to institute or maintain any action for damages relating to any breach of this Agreement by the other Party prior to the date of termination. It is the intent of the Parties that any such obligation owed by a Party to the other Party arising before the date of expiration or termination (whether the same shall be known or unknown at such date, or whether the circumstances, events, or basis of the same shall be known or unknown at such date), including royalty obligations (computed in accordance with Article III) on sales made or ordered prior to the date of termination or expiration, indemnification obligations, and confidentiality obligations, shall survive the expiration or termination of this Agreement.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Rules of Construction. This Agreement is to be interpreted in accordance with the following rules of construction:

(a) Number and Gender. All definitions of terms apply equally to both the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(b) Including; Herein; Etc. The words "include," "includes," and "including" are deemed to be followed by the phrase "without limitation." The words "herein," "hereof," and "hereunder" and words of similar import refer to this Agreement (including all Appendices) in its entirety and are not limited to any part hereof, unless the context shall otherwise require. The word "or" is not exclusive and means "and/or."

(c) Sales. The terms "sold," "sell," and "sale(s)" include leases and other transfers and similar transactions for consideration.

(d) Subdivisions and Attachments. All references in this Agreement to Articles, Sections, subsections, paragraphs, and Appendices are, respectively, references to Articles, Sections, subsections, and paragraphs of, and Appendices to, this Agreement, unless otherwise specified.

(e) References to Documents and Laws. All references to this Agreement or any Appendix hereof are to it as amended, modified, and supplemented from time to time in accordance with the terms of this Agreement. All references to (i) any other agreement or instrument or (ii) any statute, law, regulation, permit, or similar item are to it as amended and supplemented from time to time (and, in the case of a statute, law or regulation, to any corresponding provisions of successor statutes, laws, or regulations), unless otherwise specified.

(f) References to Days. Any reference in this Agreement or Order issued hereunder to a "day" or number of "days" (without the explicit qualification "Business") is a reference to a calendar day or number of calendar days. If any action or notice is to be taken or given on or by a particular calendar day, and such calendar day is not a Business Day, then such action or notice may be taken or given on the next Business Day.

(g) Examples. If, in any provision of this Agreement any example is given (through the use of the words "such as," "for example," "e.g.," or otherwise) of the meaning, intent, or operation of any provision of this Agreement, such example is intended to be illustrative only and not exclusive.

(h) Currency. Except as expressly provided herein, all prices or other monetary amounts stated in this Agreement are, and all monetary amounts stated in any report to be delivered pursuant hereto shall be, stated in United States Dollars.

(i) Participation in Drafting. Both Parties and their respective legal counsel have participated, or had the opportunity to participate, in the drafting of this Agreement, and this Agreement will be construed simply and according to its fair meaning and not strictly for or against either Party.

11.2 No Foundation Warranty.

(a) The Foundation does not warrant the validity of the Patent Rights licensed hereunder and makes no representations whatsoever with regard to the scope of the licensed Patent Rights or that such Patent Rights may be exploited by Licensee or any sublicensee without infringing other patents.

(b) THE FOUNDATION EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED AND EXPRESS WARRANTIES AND MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE PATENT RIGHTS, OR INFORMATION SUPPLIED BY THE FOUNDATION, OR OF THE LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT.

11.3 Limitation of Liability. IN NO EVENT SHALL THE FOUNDATION BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER THE FOUNDATION KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. THE FOUNDATION'S AGGREGATE LIABILITY FOR ALL DAMAGES OF ANY KIND RELATING TO THIS AGREEMENT OR ITS SUBJECT MATTER SHALL NOT EXCEED THE AMOUNT PAID BY LICENSEE TO THE FOUNDATION UNDER THIS AGREEMENT. The foregoing exclusions and limitations shall apply to all claims and actions of any kind, whether based on contract, tort (including but not limited to negligence), or any other grounds.

11.4 Indemnification and Insurance.

(a) Licensee shall indemnify, defend and hold harmless the Foundation and its current and former directors, board members, trustees, officers, employees, and agents and their respective successors, heirs and assigns (collectively, the "Indemnitees"), from and against any and all claims, liabilities, costs, expenses, damages, deficiencies, losses or obligations of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation) (collectively "Claims") based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability concerning any product, process, or service made, used, or sold pursuant to any right or license granted under this Agreement.

(b) Licensee shall, at its own expense, provide attorneys reasonably acceptable to the Foundation to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

(c) Beginning at the time any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by any sublicensee or agent of Licensee, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $2,000,000 per incident and $4,000,000 annual aggregate and naming the Indemnitees as additional insureds. During clinical trials of any such product, process, or service, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in such equal or lesser amount as the Foundation shall require, naming the Indemnitees as additional insureds. Such commercial general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions that are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to the Foundation in its sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limitation of Licensee's liability with respect to its indemnification under this Agreement.

(d) Licensee shall provide the Foundation with written evidence of such insurance upon request of the Foundation. Licensee shall provide the Foundation with written notice at least fifteen (15) days prior to the cancellation, non-renewal, or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, the Foundation shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.

(e) Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Licensee or by a sublicensee or agent of Licensee and (ii) a reasonable period after the period referred to in (e)(i) above, which period in no event shall be less than fifteen (15) years.

11.5 Limitation on Advertising and Publicity. Licensee shall not use the Foundation's or USU's name or insignia, or the name or insignia of the U.S. Government or any agency thereof, or any adaptation of the foregoing, or the name of any of Foundation's or USU's inventors, in any press release, public announcement, advertising, promotional, or sales literature without the prior written approval of the Foundation or USU, as the case may be.

11.6 No Assignment. Without the prior written approval of the Foundation in each instance, neither this Agreement nor the rights granted hereunder shall be transferred or assigned in whole or in part by Licensee to any person whether voluntarily or involuntarily, by operation of law, or otherwise. This Agreement shall be binding upon the respective successors, legal representatives, and assignees of the Foundation and Licensee.

11.7 Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of Maryland, as to all matters, including matters of validity, construction, effect, performance, and remedies, irrespective of any contrary choice of law that otherwise would be applicable under the choice of laws principles of any jurisdiction.

11.8 Compliance with Laws and Regulations. Licensee shall comply with all applicable laws and regulations, including United States laws and regulations controlling exports. Licensee agrees that it will be solely responsible for any violation of applicable laws or regulations by Licensee or its Affiliates or sublicensees, and that it will defend and hold the Foundation harmless in the event of any legal action of any nature occasioned by such violation.

11.9 Regulatory Approvals; Patent Markings. Licensee agrees (i) to obtain all regulatory approvals required for the manufacture and sale of Licensed Products and Licensed Processes and (ii) to utilize appropriate patent marking on such Licensed Products. Licensee also agrees to register or record this Agreement as is required by law or regulation in any country where the license is in effect.

11.10 Confidential Information and Intellectual Property. Except as specifically required to comply with obligations set forth in this Agreement, neither Party shall be obligated to disclose or furnish to the other Party any Confidential Information of such first Party or any confidential or proprietary information, technology, or intellectual property of any third party in such first Party's possession or control. If, however, the Parties have heretofore entered or hereafter enter into a confidential information nondisclosure agreement or similar agreement (the "NDA"), neither Party may terminate the NDA prior to the termination or expiration of this Agreement. If the Parties have not entered into an NDA, each Party agrees, for the greater of a period of five (5) years after each disclosure or during the pendency of this Agreement, to maintain in confidence all Confidential Information disclosed to it by the other Party and to protect such Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the receiving Party uses to protect its own similar confidential information.

11.11 Headings. The article, section, and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define, or limit the scope, extent, or intent of this Agreement.

11.12 Counterpart Execution. This Agreement and any modification or amendment thereof may be executed in counterparts, both of which shall be considered one and the same agreement, and shall become effective when such counterparts have been signed by each of the Parties and delivered to the other Party.

11.13 Waivers; Remedies Generally. The observance of any term of this Agreement may be waived (whether generally or in a particular instance and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver will be effective only if in a writing signed by the Party against which such waiver is to be asserted. Except as otherwise provided in this Agreement, no failure or delay of either Party in exercising any power, right, or remedy under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any such right, power, or remedy, preclude any other or further exercise thereof or the exercise of any other right, power, or remedy. A waiver by either Party shall be limited to the specific instance in which it is given and, therefore, any waiver by either Party of any obligation of the other Party under or breach by the other Party of this Agreement or of any power, right, or remedy of the waiving Party shall not be a waiver of any other obligation or further or future performance of the same obligation, of any other or succeeding breach, of any other or further exercise of such power, right, or remedy or any other power, right, or remedy.

11.14 Severability. To the extent that any provision of this Agreement shall be judicially unenforceable in any one or more jurisdictions, such provision shall not be affected with respect to any other jurisdiction, each provision with respect to each jurisdiction being construed as several and independent. If any term or provision of this Agreement or the application thereof to any person or circumstance is, to any extent, declared or found to be illegal, unenforceable, or void, then both Parties will be relieved of all obligations arising under such term or provision, but only to the extent that such term or provision is illegal, unenforceable, or void, it being the intent and agreement of the Parties that this Agreement will be deemed amended by modifying such term or provision to the extent necessary to make it legal and enforceable while preserving its intent or, if that is not possible, by substituting therefor another term or provision that is legal and enforceable and achieves the same objective. If the remainder of this Agreement will not be affected by such declaration or finding and is capable of substantial performance, then each term and provision not so affected will be enforced to the extent permitted by law. If necessary to effect the intent of the Parties, the Parties will negotiate in good faith to amend this Agreement to replace the unenforceable language with enforceable language that as closely as possible reflects such intent and to amend any other term or provision thereby rendered incapable of substantial performance or otherwise affected thereby to the extent necessary to permit the practical realization, insofar as legally possible, of the intent of the Parties.

11.15 Relationship of the Parties; Disclaimer of Agency.

(a) Independent Contractors. In entering into and carrying out this Agreement, the Parties will be acting solely as independent contractors. Nothing in this Agreement creates, has created, or will create any partnership, joint venture, or other business association between the Parties, nor any duties or responsibilities of partners, venturers, or members of a business association.

(b) No Agency. Except for provisions in this Agreement expressly authorizing one Party to act for the other, this Agreement will not constitute either Party as a legal representative or agent of the other Party, nor will either Party have the right or authority to assume, create, or incur any liability or any obligation of any kind, expressed or implied, against or in the name or on behalf of the other Party unless otherwise expressly permitted by such Party.

11.16 No Third Party Beneficiaries. The representations, warranties, covenants, and undertakings contained in this Agreement are for the sole benefit of the Parties, their sublicensees, and the Parties' permitted successors and assigns and shall not be construed as creating any third party beneficiaries of this Agreement or as conferring any rights whatsoever on any third party.

11.17 Notices. Unless otherwise expressly agreed by the Party receiving notice, any notice, demand, or other communication required or permitted to be given by either Party under any provision of this Agreement must be in writing, in the English language, and mailed (certified or registered mail, postage prepaid, return receipt requested) or sent by hand or overnight courier, or by facsimile (with acknowledgment received), charges prepaid and addressed to the intended recipient at such Party's address set forth below, or to such other address or number as such Party may from time to time specify by notice to the other Party as provided in this Section. All notices and other communications given in accordance with the provisions of this Agreement will be deemed to have been given and received (i) when actually delivered by hand, by mail, or by courier, or (ii) when transmitted by facsimile (with acknowledgment received and a copy of such notice is sent no later than the next Business Day by a reliable overnight or two-day courier service, with acknowledgment of receipt).

If to Licensee:

Norwell, Inc.
415 Jackson Hill
Houston, TX 77007
713-862-5478

If to the Foundation:
The Henry M. Jackson Foundation for
the Advancement of Military Medicine, Inc.
ATTN: General Counsel
1401 Rockville Pike, Suite 600
Rockville, MD 20852
Fax: 301-294-8130

11.18 Disputes. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the Parties shall try to settle such conflict amicably between themselves. Subject to the limitation stated in the final sentence of this Section, any such conflict that the Parties are unable to resolve promptly shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statute of limitations. Such arbitration shall be held in Montgomery County, Maryland. The award through arbitration shall be final and binding. Either Party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either Party may, without recourse to arbitration, assert against the other Party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.

11.19 Entire Agreement; Modifications. This Agreement constitutes the complete agreement between the Parties concerning the subject matter hereof and replaces any prior oral or written communications between the Parties. There are no conditions, understandings, agreements, representations, or warranties, express or implied, that are not specified herein, and neither Party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed by the Parties in writing. Any purported modification or amendment of the express terms or provisions of this Agreement shall be effective only if contained in a written instrument signed by each Party.

11.20 Publications. Prior to a Party's submission for publication or presentation technical developments and/or research findings related to the Patent Rights licensed hereunder, the publishing or presenting Party shall provide the other Party with at least thirty (30) days for review and comment upon the manuscript or other material proposed for publication. In addition, if requested by the other Party, the publishing or presenting Party will withhold such submission for publication or presentation for an additional thirty (30) days to allow for filing a patent application or taking such measures, as the Party deems appropriate to establish and preserve its proprietary rights in the information in the manuscript or presentation.

THE FOUNDATION AND LICENSEE HAVE READ THIS AGREEMENT INCLUDING ALL APPENDICES HERETO AND AGREE TO BE BOUND BY ALL THE TERMS AND CONDITIONS HEREOF AND THEREOF.

IN WITNESS WHEREOF, the Parties have entered into this License Agreement as of the date first above set forth.

THE HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE, INC.

/s/ John W. Lowe
John W. Lowe
President & CEO

13 May 2009
Date

NORWELL, INC.

/s/ Eric Rothe
Eric Rothe
President & CEO

5/13/2009
Date

APPENDIX A

The following **patent applications are** included in the Patent Rights:

Patent 1 -

Title: Vaccine for the Prevention of Breast Cancer Recurrence
Inventors: Peoples and Ponniah
Provisional Patent Application No.: 61/121,220
Filing date: 10 December 2008

Patent 2 -

Title: Targeted Identification of Immunogenic Peptides
Inventors: Peoples, Ponniah, Flora and Storrer

as described in U.S. Patent Application No. 12/045,402 filed on 3/10/2008 and Australian Application No. 2008201427 filed on 3/28/2008, both claiming priority to U.S. Provisional Application No. 60/714,865 filed on 09/08/2005 and International Application No. PCT/US2006/035171 filed on 09/08/2006; and

as described in International Application No. PCT/US2006/035171 filed on 09/08/2006 and all corresponding National Stage Applications including but not limited to Japanese Patent Application No. 2008-530244, European Patent Application No. 06824918.4 filed on 3/31/2008, and Canadian Patent Application No. 2,622,036 filed on 3/10/2008; and

as described in International Application No. PCT/GB2008/050227 filed 03/28/2008 and all its corresponding National Stage Applications; and

FIRST AMENDMENT

TO

EXCLUSIVE LICENSE AGREEMENT

THIS FIRST AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT ("First Amendment") is made and entered into as of the date of the last signature below by and between Norwell, Inc., a corporation organized under the laws of the State of Delaware and having its principal offices at 415 Jackson Hill, Houston, Texas ("Licensee") and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a tax-exempt corporation organized under the laws of the State of Maryland and having its principal offices at 1401 Rockville Pike, Suite 600, Rockville, Maryland ("Foundation") Licensee and Foundation are sometimes referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, the Parties entered into an Exclusive License Agreement with an effective date of April 24, 2009 (the "Agreement");

WHEREAS, the Parties desire to amend certain terms and conditions of the Agreement.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth in this First Amendment, and other good and valuable consideration, the receipt and sufficiency of which are expressly acknowledged, the Parties, intending to be legally bound, agree as follows:

1. Section 1.12 of the Agreement shall be deleted in its entirety and replaced with the following:

> 1.12 "Nonroyalty Sublicense Income" means all sublicense issues fees, sublicense maintenance fees, sublicense milestone payments, and similar non-royalty upfront fees and milestone payments (including the purchase of equity directly related to a sublicense) made by sublicensees to Licensee on account of sublicenses pursuant to this Agreement. However, Non-royalty Sublicense Income does not include payments to Licensee from sublicensees for the express purpose of being specifically allocated to support research, development, clinical trial, and manufacturing of Licensed Products or Licensed Processes.

2. Section 1.18, as expressed below, is added to the Agreement:

> 1.18 "GP2 IND" means the Investigational New Drug application belonging to Dr. George Peoples known as Her2 – Neu Peptide (GP2) with Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) Adjuvant, BB-IND#11730.

3. Section 3.2 of the Agreement shall be deleted in its entirety and replaced with the following:

3.2 No later than thirty (30) days after the close of Licensee's Series A financing Licensee shall transfer to Foundation an equity position in Licensee equal to Ten percent (10%) of the outstanding shares of Licensee at that time.

4 Section 3.3 of the Agreement shall be deleted in its entirety and replaced with the following:

3.3 Licensee shall pay to the Foundation semi-annually, within sixty (60) days after each calendar half year ending June 30 and December 31, the greater of: (i) a semi-annual minimum royalty of Fifty Thousand dollars ($50,000.00); or (ii) a running royalty of Five percent (5%) of Net Sales by Licensee and sublicensees in a given jurisdiction covered by at least one Valid Claim existing in such jurisdiction and Two and One-Half percent (2.5%) of Net Sales by Licensee and sublicensees in a given jurisdiction not covered by any Valid Claim existing in such jurisdiction. In the case of sublicenses, Licensee shall also pay to the Foundation a royalty of Fifteen percent (15%) of Non-royalty Sublicense Income until the Commencement of the Phase III Clinical Trial. From the Commencement of the Phase III Clinical Trial and continuing thereafter, Licensee shall pay to the Foundation a royalty of Ten percent (10%) of Non-royalty Sublicense Income. Commencement of the Phase III Clinical Trial means the enrollment of the first patient in the Phase III Clinical Trial.

5. There is a typographical error in Section 3.4 of the Agreement. The reference to Section 3.2 in Section 3.4 should be a reference to Section 3.3. Accordingly, Section 3.4 of the Agreement shall be deleted in its entirety and replaced with the following corrected version:

3.4 No later than January 1 of each calendar year after the Effective Date of this Agreement, Licensee shall pay to the Foundation the following non-refundable license maintenance royalties. Such maintenance royalty payments may be credited against running royalties due (pursuant to Section 3.3) for that calendar year only, and Royalty Reports (pursuant to Section 5.3) shall reflect such a credit. Such payments shall not be credited against any milestone payments nor against royalties due for any other calendar year.

Patent 1:	
January 1, 2010	$12,500.00
January 1, 2011	$37,500.00
January 1 of each year thereafter until the filing of an NDA for a Licensed Product or Licensed Process utilizing Patent 1	$25,000.00
Patent 2:	
January 1, 2010	$12,500.00
January 1, 2011	$37,500.00
January 1 of each year thereafter until the filing of an NDA for a Licensed Product or Licensed Process Utilizing Patent 2	$25,000.00

6. Section 3.5 of the Agreement shall be deleted in its entirety and replaced with the following:

3.5 Licensee shall pay to the Foundation the following milestone payment(s) within thirty (30) days after the associated milestone occurs (in each instance):

Licensed Product or Licensed Process Utilizing Patent 1:	
Commencement of Phase III Clinical Trial	$150,000.00
Filing of an NDA	$600,000.00
Marketing Approval	$850,000.00
First commercial sale	$1,250,000.00

Licensed Product or Licensed Process Utilizing Patent 2:	
Commencement of Phase III Clinical Trial	$150,000.00
Filing of an NDA	$600,000.00
Marketing Approval	$850,000.00
First commercial sale	$1,250,000.00

7. Section 3.6 of the Agreement shall be deleted in its entirety and replaced with the following:

3.6 Licensee agrees to pay Foundation Three Million Dollars ($3,000,000.00) in support of the GP2 breast cancer vaccine Phase II clinical trial (hereinafter "Clinical Trial Financial Support"). Licensee acknowledges that the GP2 breast cancer vaccine Phase II clinical trial has already commenced and that the Parties intend Licensee's Clinical Trial Financial Support to cover past, ongoing, and future expenses associated with the GP2 breast cancer vaccine Phase II clinical trial. Prior to 5:00pm (EDT) on February 9, 2010, Licensee shall pay Foundation Three Hundred Thousand Dollars ($300,000.00) towards its Clinical Trial Financial Support obligation. Beginning no later than July 1, 2010 and continuing on a quarterly basis thereafter, Licensee shall pay Foundation additional amounts towards Licensee's Clinical Trial Financial Support obligation in accordance with the following schedule:

July 1, 2010	$150,000.00
October 1, 2010	$150,000.00
January 1, 2011	$350,000.00
April 1, 2011	$350,000.00
July 1, 2011	$350,000.00
October 1, 2011	$350,000.00
January 1, 2012	$250,000.00
April 1, 2012	$250,000.00
July 1, 2012	$250,000.00
October 1, 2012	$250,000.00

In the event the GP2 breast cancer vaccine Phase II clinical trial is terminated prior to completion of the trial, Licensee's Clinical Trial Financial Support obligation will be adjusted proportionally to correspond to the reduced number of patients enrolled.

8. Section 4.2 of the Agreement shall be deleted in its entirety and replaced with the following:

4.2 Within thirty-six (36) months of the Effective Date, Licensee shall raise at least Three Million Dollars ($3,000,000.00) in funding (whether by debt, equity, or grant) and provide evidence of same to Foundation.

9. Subsection 5.3(c) of the Agreement shall be deleted and replaced with the following:

(c) Late payments shall be subject to a charge of one and one-half percent (1-1/2%) per month ("Late Charge"). The Late Charge shall accrue upon the first day the payment is past due and be reassessed at the beginning of each subsequent month the payment continues to remain unpaid. To illustrate, if a payment is due on July 1st and the payment is not paid by July 1st, a Late Charge will accrue and become due on July 2nd. If the payment remains unpaid on August 1st, another Late Charge will accrue and so on.

10. Section 5.6 of the Agreement shall be deleted in its entirety and replaced with the following:

5.6 Foundation shall make available to the Licensee all preclinical, manufacturing, and clinical data and information in its possession related to the Patent Rights licensed hereunder. The Parties acknowledge and agree that the GP2 IND shall remain with Dr. George Peoples unless and until Licensee and Dr. Peoples agree to transfer the IND to Licensee.

11. Section 5.7, as expressed below, is added to the Agreement:

5.7 No later than forty-five (45) days after the end of each calendar quarter that the GP2 breast cancer vaccine Phase II clinical trial continues, Foundation shall provide to Licensee a written report on the progress of the GP2 breast cancer vaccine Phase II clinical trial.

12. Section 5.8, as expressed below, is added to the Agreement:

5.8 Licensee shall provide to Foundation and Foundation shall provide to Licensee, without delay, copies of all FDA submissions and correspondence each has in its possession related to Licensed Products and Licensed Processes.

13. Section 7.2 of the Agreement shall be deleted in its entirety and replaced with the following:

7.2 Licensee shall reimburse the Foundation for all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 1 ("Patent 1 Patent Expenses").

(a) Licensee shall reimburse Foundation for all Patent 1 Patent Expenses incurred prior to January 1, 2011 no later than April 28, 2011. On or about March 1, 2011, Foundation shall provide Licensee with an invoice that describes the outstanding Patent 1 Patent Expenses incurred prior to January 1, 2011. Licensee shall pay the invoice in full no later than April 28, 2011.

(b) Notwithstanding the reimbursement schedule in Section 7.2(a), upon Licensee raising Five Million Dollars ($5,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 1 Patent Expenses the Foundation has incurred.

(c) Upon the first reimbursement of Patent 1 Patent Expenses based on 7.2(a) or 7.2(b), Licensee shall thereafter reimburse Foundation for all Patent 1 Patent Expenses on a continuing basis within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late Payment of these invoices shall be subject to interest charges of one and one-half percent (1 ½%) per month.

14. Section 7.3 of the Agreement shall be deleted in its entirety and replaced with the following:

7.3 Licensee shall reimburse the Foundation for fifty percent (50%) of all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 2 ("Patent 2 Patent Expenses").

(a) Licensee shall reimburse Foundation for all Patent 2 Patent Expenses incurred prior to January 1, 2011 no later than April 28, 2011. On or about March 1, 2011, Foundation shall provide Licensee with an invoice that describes the outstanding Patent 2 Patent Expenses incurred prior to January 1, 2011. Licensee shall pay the invoice in full no later than April 28, 2011.

(b) Notwithstanding the reimbursement schedule in Section 7.3(a), upon Licensee raising Five Million Dollars ($5,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 2 Patent Expenses the Foundation has incurred.

(c) Upon the first reimbursement of Patent 2 Patent Expenses based on 7.3(a) or 7.3(b), Licensee shall thereafter reimburse Foundation for all Patent 2 Patent Expenses on a continuing basis within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late Payment of these invoices shall be subject to interest charges of one and one-half percent (1 ½%) per month.

15. Subsection 10.2(a) of the Agreement shall be deleted and replaced with the following:

(a) if Licensee does not make any payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with subsection 5.3(c)) within sixty (60) days after the receipt of notice in writing of such non-payment by the Foundation.

16. Subsection 10.2(e) of the Agreement shall be deleted and replaced with the following:

(e) if Licensee fails to raise at least Three Million Dollars ($3,000,000.00) in funding (whether by debt, equity, or grant) within thirty-six (36) months of the Effective Date in accordance with Section 4.2 and provide evidence of same to the Foundation within thirty (30) days thereafter.

17. In consideration for the Foundation agreeing to delay its recovery of Licensee's Clinical Trial Financial Support and reimbursement by Licensee of Patent 1 and Patent 2 Patent Expenses, Licensee agrees to pay Foundation Forty Thousand

Dollars ($40,000.00) ("Delay Fees"), which shall be made in calendar year 2011 in four installments of Ten Thousand Dollars ($10,000.00) each, the dates of such Delay Fee payments corresponding to the dates of Licensee's Clinical Trial Financial Support payments (i.e., January 1, 2011, April 1, 2011, July 1, 2011, and October 1, 2011).

18. The Parties acknowledge and agree that, except as set forth in this First Amendment, the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this First Amendment to be executed by their respective duly authorized representatives.

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.

Name: John W. Lowe
Title: President & CEO
Date: Feb 12, 2010

Norwell, Inc.

Name: Snehal S. Patel
Title: Chief Financial Officer
Date: February 9, 2010

SECOND AMENDMENT

TO

EXCLUSIVE LICENSE AGREEMENT

THIS SECOND AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT ("Second Amendment") is made and entered into as of the date of the last signature below by and between Norwell, Inc., a corporation organized under the laws of the State of Delaware and having its principal offices at 415 Jackson Hill, Houston, Texas ("Licensee") and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., a tax-exempt corporation organized under the laws of the State of Maryland and having its principal offices at 1401 Rockville Pike, Suite 600, Rockville, Maryland ("Foundation"). Licensee and Foundation are sometimes referred to herein individually as a "Party" or collectively as the "Parties".

WHEREAS, the Parties entered into an Exclusive License Agreement with an effective date of April 24, 2009 (the "Original Agreement");

WHEREAS, the Parties amended certain terms and condition of the Original Agreement by virtue of the First Amendment to Exclusive License Agreement, effective February 17, 2010 (the "First Amendment") (the Original Agreement as amended by the First Amendment hereinafter referred to as the "Agreement");

WHEREAS, the Parties desire to amend certain terms and conditions of the Agreement.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth in this Second Amendment, and other good and valuable consideration, the receipt and sufficiency of which are expressly acknowledged, the Parties, intending to be legally bound, agree as follows:

1. Section 3.4 of the Agreement shall be deleted in its entirety and replaced with the following:

   3.4 Licensee shall pay to the Foundation the non-refundable license maintenance royalties listed below. Such maintenance royalty payments may be credited against running royalties due (pursuant to Section 3.3) for that same calendar year only, and Royalty Reports (pursuant to Section 5.3) shall reflect such a credit. Such payments shall not be credited against any milestone payments nor against royalties due for any other calendar year.

Patent 1:	
January 1, 2010	$12,500.00
July 1, 2011	$37,500.00
January 1 of each year thereafter until the filing of a NDA for a Licensed Product or Licensed Process Utilizing Patent 1	$25,000.00

Patent 2:	
January 1, 2010	$12,500.00
July 1, 2011	$37,500.00
January 1 of each year thereafter until the filing of a NDA for a Licensed Product or Licensed Process Utilizing Patent 2	$25,000.00

2. Section 3.6 of the Agreement shall be deleted in its entirety and replaced with the following:

3.6 Licensee agrees to pay Foundation Three Million Dollars ($3,000,000.00) in support of the GP2 breast cancer vaccine Phase II clinical trial (hereinafter "Clinical Trial Financial Support"). Licensee acknowledges that the GP2 breast cancer vaccine Phase II clinical trial has already commenced and that the Parties intend Licensee's Clinical Trial Financial Support to cover past, ongoing, and future expenses associated with the GP2 breast cancer vaccine Phase II clinical trial. Prior to 5:00pm (EDT) on February 9, 2010, Licensee shall pay Foundation Three Hundred Thousand Dollars ($300,000.00) towards its Clinical Trial Financial Support obligation. Beginning no later than July 1, 2010 and continuing on a quarterly basis thereafter, Licensee shall pay Foundation additional amounts towards Licensee's Clinical Trial Financial Support obligation in accordance with the following schedule:

July 1, 2010	$150,000.00
October 1, 2010	$150,000.00
January 1, 2011	$200,000.00
April 1, 2011	$200,000.00
July 1, 2011	$350,000.00
October 1, 2011	$350,000.00
January 1, 2012	$325,000.00
April 1, 2012	$325,000.00
July 1, 2012	$325,000.00
October 1, 2012	$325,000.00

In the event the GP2 breast cancer vaccine Phase II clinical trial is terminated prior to completion of the trial, Licensee's Clinical Trial Financial Support obligation will be adjusted proportionally to correspond to the reduced number of patients enrolled.

3. Section 7.2 of the Agreement shall be deleted in its entirety and replaced with the following:

7.2 Licensee shall reimburse the Foundation for all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 1 ("Patent 1 Patent Expenses").

(a) Licensee shall reimburse Foundation for all Patent 1 Patent Expenses billed to Foundation prior to May 1, 2011 no later than July 1, 2011. On or about May 31, 2011, Foundation shall provide Licensee with an invoice that describes the

outstanding Patent 1 Patent Expenses billed to Foundation prior to May 1, 2011. Licensee shall pay the invoice in full no later than July 1, 2011.

(b) Notwithstanding the reimbursement schedule in Section 7.2(a), upon Licensee raising Five Million Dollars ($5,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 1 Patent Expenses the Foundation has incurred.

(c) Upon the first reimbursement of Patent 1 Patent Expenses based on 7.2(a) or 7.2(b), Licensee shall thereafter reimburse Foundation for all Patent 1 Patent Expenses on a continuing basis within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late Payment of these invoices shall be subject to interest charges of one and one-half percent (1 ½%) per month.

4. Section 7.3 of the Agreement shall be deleted in its entirety and replaced with the following:

7.3 Licensee shall reimburse the Foundation for fifty percent (50%) of all reasonable expenses the Foundation has incurred or will incur for the preparation, filing, prosecution, and maintenance of Patent Rights associated with Patent 2 ("Patent 2 Patent Expenses").

(a) Licensee shall reimburse Foundation for all Patent 2 Patent Expenses billed to Foundation prior to May 1, 2011 no later than July 1, 2011. On or about May 31, 2011, Foundation shall provide Licensee with an invoice that describes the outstanding Patent 2 Patent Expenses billed to Foundation prior to May 1, 2011. Licensee shall pay the invoice in full no later than July 1, 2011.

(b) Notwithstanding the reimbursement schedule in Section 7.3(a), upon Licensee raising Five Million Dollars ($5,000,000.00) or more in funding (whether by debt, equity, or grant), Licensee shall reimburse Foundation for all outstanding Patent 2 Patent Expenses the Foundation has incurred.

(c) Upon the first reimbursement of Patent 2 Patent Expenses based on 7.3(a) or 7.3(b), Licensee shall thereafter reimburse Foundation for all Patent 2 Patent Expenses on a continuing basis within thirty (30) days after Licensee's receipt of invoices from the Foundation. Late Payment of these invoices shall be subject to interest charges of one and one-half percent (1 ½%) per month.

5. The payment of Delay Fees as provided for in Section 17 of the First Amendment is amended as follows:

In consideration for the Foundation agreeing to delay its recovery of Licensee's Clinical Trial Financial Support and reimbursement by Licensee of Patent 1 and Patent 2 Patent Expenses, Licensee agrees to pay Foundation Sixty Thousand Dollars ($60,000.00) ("Delay Fees"), which shall be made in six installments of Ten Thousand Dollars ($10,000.00) each by the following dates: July 1, 2011, October 1, 2011, January 1, 2012, April 1, 2012, July 1, 2012, and October 1, 2012.

6. The Parties acknowledge and agree that, except as set forth in this Second Amendment, the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Second Amendment to be executed by their respective duly authorized representatives.

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.

Name: John W. Lowe
Title: President & CEO
Date: 9/24/10

Norwell, Inc.

Name: Snehal S. Patel
Title: Chief Financial Officer
Date: 9/24/10

AMERICAN ARBITRATION ASSOCIATION
Commercial Arbitration Tribunal

HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE, INC., Claimant,	)	
v.	)	Case: 16 193 Y 00667 12
NORWELL, INC., Respondent.	)	

AWARD OF ARBITRATORS

WE, THE UNDERSIGNED ARBITRATORS, having been designated in accordance with the arbitration agreement entered into between the above-named parties, and having been duly sworn, and having duly heard the proofs and allegations of the Parties, AWARD, as follows:

I. Procedural Background

This matter was initiated by the filing of a Demand for Arbitration by Claimant Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") on November 27, 2012 with the American Arbitration Association. Respondent Norwell, Inc. ("Norwell") filed its Answering Statement and Counterclaim on December 14, 2012. HJF filed a Reply to Norwell's counterclaims on January 14, 2013, and Norwell filed an Amended Answer and Counterclaims on March 6, 2013. The parties engaged in discovery and the case proceeded to final hearing before the Panel on October 14 – 25, 2013. The parties submitted post-hearing briefs and supplemental submissions, and the Panel finally closed the record in this matter on February 24, 2014.

II. History of the Dispute

HJF entered into two License Agreements (in 2009 and 2010) with Norwell regarding an experimental vaccine to prevent recurrence of breast cancer called GP2. The 2009 License Agreement was amended twice in 2010. The 2009 License Agreement granted GP2 patent rights to Norwell, as exclusive licensee, and also contained provisions whereby Norwell would sponsor an ongoing clinical trial of GP2 being conducted by Dr. George Peoples, an active duty colonel in the United States Army

and a Director of Surgery of the Uniformed Services University of the Health Sciences ("USU"). (C-009) It is the 2009 License Agreement that is at the core of the dispute in this case and references to the "License Agreement" and the "contract" refer to the 2009 License Agreement unless otherwise indicated.

Initially, the parties discussed an arrangement in which at least 180 patients would be enrolled in the GP2 clinical trial, at a cost of $15,000 per patient for a total support obligation for Norwell of $2,700,000. The contract went through several iterations reflecting the foregoing per patient pricing model, but the parties eventually signed a contract in which the 180 patient/$2,700,000 references were removed and replaced with a flat $3,000,000 obligation for Norwell to support the clinical trial. The $3,000,000 was to cover 180-300 patients enrolled in the GP2 study as necessary to reach statistical significance.

One of Norwell's obligations under the License Agreement was to raise $3,000,000 in funding within 36 months of the Effective Date. (Section 4.2 of the License Agreement (as amended)) A potential source of new capital was from the Texas Emerging Technology Fund (ETF), a Texas state fund that makes sizeable non-dilutive monetary grants to companies that agree to locate their operations in Texas. During the course of its dealings with HJF, Norwell applied to the ETF for a $2,500,000 grant.

The License Agreement does not refer to any financial arrangement between Norwell and Dr. Peoples, but at the time Norwell entered into the License Agreement both Norwell and Dr. Peoples expected that he would have at least an advisory role in Norwell and a monetary interest in its attempts to commercialize GP2. After the License Agreement was signed, Dr. Peoples spent a considerable amount of time advising and assisting Norwell in presenting the GP2 story, especially to the ETF. However, in addition to GP2, Dr. Peoples was actively researching two other peptides similar to GP2 - AE37 and E75 - being developed by Antigen Express and Galena (after acquiring Apthera Inc. in March 2011), both competitors of Norwell.

Eventually, the ETF regional committee recommended Norwell for the $2,500,000 grant; however, at the ETF Governor's Advisory Committee the recommendation was not accepted. The Committee had several concerns. The primary concern expressed was that Dr. Peoples' loyalties were

divided among the three companies. Principal among the ETF concerns was that Norwell distance itself from Dr. Peoples by assuming control of the GP2 clinical trial IND.

Dr. Jaye Thompson, a Ph.D. statistician with extensive experience with biostatistics, clinical trials, and the FDA IND and drug approval process, and a member of the ETF Governor's Advisory Committee, testified that Dr. Peoples had expressly represented to the ETF board that once Norwell had hired a qualified clinical trial manager, he would assign the GP2 IND to Norwell. Following the denial by the Advisory Committee, Norwell engaged the services of Dr. Kerstin Menander as its scientific advisor. Dr. Menander has both a Ph.D. in histology and a medical degree and is well qualified to take over management of the clinical trial. But Dr. Peoples refused to transfer the IND to Norwell unless it paid him a total of $500,000 for the IND, the clinical trial data, and the FDA correspondence. Norwell balked at the payment of the money demanded by Dr. Peoples and offered him warrants for Norwell stock, instead, which he declined to accept. If Dr. Peoples would not transfer the IND to Norwell, then Norwell would be required to obtain its own IND from the FDA. According to Drs. Thompson and Menander, to obtain such an IND Norwell would need all the clinical trial data in auditable form and all the FDA correspondence relating to the GP2 trial. Norwell had some, but not all, of the data and correspondence, which Dr. Peoples refused to provide without payment and which, for reasons discussed below, HJF failed to provide.

It is undisputed that around the time of the impasse with Dr. Peoples, Norwell did not make a portion of the $3,000,000 clinical trial support payments required under the 2009 License Agreement and that HJF terminated the contract with Norwell on the grounds of non-payment over Norwell's objections. HJF subsequently terminated the 2010 License Agreement, as well. HJF seeks a declaratory award that the License Agreements were properly terminated and asks to recover damages in the amount of $3,029,364.06 that HJF asserts resulted from Norwell's failure to comply with its payment obligations under the License Agreements.

In its defense, Norwell asserts that HJF breached the contracts and that Norwell was therefore justified in withholding payments under the License Agreements. Furthermore, in its amended

counterclaim, Norwell seeks affirmative relief based upon three claims: breach of contract, fraudulent misrepresentation, and violation of the Maryland Uniform Trade Secrets Act. Norwell argues that HJF's breaches of the contracts relieved it from the obligation to make the payments at issue under the License Agreements. Norwell asserts that it suffered damages as a result of HJF's conduct for which it is entitled to recover damages.

As referenced above, Norwell also argues that it was fraudulently induced to enter into the License Agreements by HJF and that HJF violated the Maryland Uniform Trade Secrets Act when Dr. Peoples published data that included GP2 clinical trial data Norwell considered to be confidential.

Norwell asks the Panel to reinstate the 2009 License Agreement, to award certain other declaratory relief, to declare that the 2010 License Agreement is invalid, and to award damages to Norwell totaling $23,970,924.

III. Contract Claims

A. HJF's Claims

HJF argues that the case is a simple breach of contract case for non-payment under the 2009 and 2010 License Agreements. Norwell repeatedly was late in making its payments under the License Agreements and received seven notices of default for non-payment from HJF during the course of the contracts. The first five instances of late payment were cured by Norwell or waived by HJF after payment of late fees. The last two notices of default were not cured, however, and HJF terminated the 2009 License Agreement on March 16, 2012 (C-380) and the 2010 License Agreement on May 1, 2012 (C-388). Whether these terminations were justified is dependent on whether HJF committed a material breach of the License Agreements that excused Norwell from performance under the contracts prior to Norwell's failure to cure its non-payment.

B. Norwell's Defenses and Counterclaims

1) Breach of Contract

Norwell asserts in its counterclaim that HJF breached the contract (i) by overcharging for the phase II study (by failing to enroll patients at the rate represented to Norwell during negotiations, by

improperly mixing patients from the control group of another ongoing study (AE37) with the GP2 controls thereby adversely affecting GP2's showing of a statistically significant therapeutic benefit, by failing to perform circulating tumor cell (CTC) assays on patients enrolled in the trial, by charging Norwell for patient enrollment already paid for by Antigen Express (sponsor of the AE37 trial), and by prematurely terminating enrollment of patients in the GP2 clinical trial, (ii) by breaching the publications provision of the contract (by failing to provide timely notice of USPTO office actions relating to the GP2 patent, by failing to provide timely notice of intended publication of GP2 data, and by publishing confidential GP2 data over the objection of Norwell), and (iii) by not providing Norwell with the IND, FDA correspondence, and data related to GP2 (by failing to transfer (or causing Dr. Peoples to transfer) the IND for the GP2 study to Norwell after Norwell hired Dr. Menander, and by failing to provide all clinical data and FDA correspondence to Norwell on a timely basis as required by the License Agreement. Norwell argues that these breaches by HJF, collectively or individually, relieved Norwell from its obligation to make payments under the License Agreements.

We address Norwell's claims of breach by HJF in the order presented in Norwell's post-hearing brief.

a) Breach of the Payment Terms under the 2009 License Agreement

Norwell avers that HJF violated the payment terms of the License Agreement in two ways: first, by failing to conduct a CTC assay on all patients enrolled in the GP2 arm of the study and, second, by charging Norwell for patients that Norwell asserts were never recruited.

With respect to the CTC assays, Norwell claims that its clinical trial support was predicated on a cost of $15,000 per patient, which included a CTC assay to be performed on each patient in the study. Norwell points to correspondence with Dr. Peoples relating to the cost of the clinical trial that Norwell would sponsor under the License Agreement. In an email exchange in December 2008 between Eric Rothe of Norwell and Dr. Peoples (R-62), Mr. Rothe expressly asks for confirmation that the cost of the trial will be $10,000 per patient including a CTC assay. Dr. Peoples responds that $10,000 is a "bare bones" cost without the CTC. He states he expects the trial will cost $15,000-$20,000 per patient.

Although he does not specifically reference the CTC assay in his revised number, he does not exclude the CTC assay in his revised number given in response to Mr. Rothe's explicit inquiry regarding the inclusion of a CTC assay. Norwell may have been justified in understanding Dr. Peoples' response to mean that a CTC assay would be included at a cost of $15,000 to $20,000 per patient; however, the CTC assay was not referenced in any manner in the License Agreement provisions regarding sponsored research that followed in 2009. The 2009 License Agreement has an integration clause at §11.19 that precludes incorporation of a CTC requirement based on Norwell's understanding from its 2008 discussions with Dr. Peoples.

Norwell further claims that by making payments to HJF on a fixed schedule it was overcharged under the License Agreement, because it was paying for patients that had not yet been enrolled in the clinical trials. Norwell points to the slow pace of enrollment and says, in effect, that it was wrongfully required to pay for patients in advance of their enrollment. According to Norwell, since HJF knew Norwell was a cash-strapped startup, HJF should have allowed it to make its payments in step with the pace of enrollment. The problem with Norwell's argument is that there is no requirement in the License Agreement that the schedule of Norwell's sponsorship payments is tied to the pace of patient enrollment.

Norwell argues that HJF also breached the payment terms of the agreement, because Norwell's payments paid for patients enrolled as controls in the AE37 arm of the clinical trial and that these patients were also paid for by Antigen Express, meaning that HJF was paid twice for the same patients when they were counted in the GP2 control group. Again, Norwell's argument does not find support in the terms of the License Agreement. Regardless of how patients were recruited into the GP2 arm of the clinical trial and regardless of the number of GP2 patients enrolled at any given point in the study, Norwell had a $3,000,000 funding obligation for the trial, payable in specified installments that were not dependent on enrollment rate or patient count at the time of each payment.

The Panel rejects Norwell's assertion that HJF breached the payment terms of the License Agreements.

b. Failure to Provide Timely Notice of USPTO Office Action on Patent

Norwell claims that the Foundation failed to provide it with timely notice, of correspondence from the USPTO rejecting the claims in a pending patent application related to Trastuzumab (tradename Herceptin) + GP2. Section 7.4 requires that "Each Party shall provide to the other prompt notice as to all matters that come to its attention and that may affect the preparation, filing, prosecution, or maintenance of any such patent application or applications".

The Foundation was also required to "consult with Licensee as to the preparation, filing, prosecution and maintenance of such patent applications and patents and shall furnish to Licensee copies of documents relevant to any such preparation, filing, prosecution or maintenance " (Sec. 7.1).

It is undisputed that the Foundation received a letter from the USPTO in August 2011 rejecting the claims in the Herceptin + GP2 patent application (HMJ-115-US). The Foundation engaged patent counsel to respond to the letter but did not notify Norwell of the USPTO letter until September 30, 2011. At that time, the Foundation provided Norwell a copy of its counsel's memorandum "describing in detail the office action, as well as a draft response..." to the USPTO requesting Norwell's comments "no later than COB on Tuesday October 4th. We want to file by Oct. 5th in order to avoid any additional fees and any subtraction from any patent term adjustment that may accrue during the pendency of this application." (R-45.)

Mr. Patel testified, and in its post- hearing brief Norwell argues, that this notice was untimely and "if given adequate time, Norwell could have contacted and engaged its preferred patent attorney, DLA Piper, to assist with the matter." (Patel Depo, 64:5-23; R-45.)

The Panel finds that the Foundation did not provide "prompt notice" of the USPTO letter to Norwell as required by Section 7.4. However, Norwell has failed to prove any damages in connection with this late notice from HMJ. There is no evidence that Norwell was damaged in any manner from HJF's failure or that Norwell took steps to prevent any potential damage caused by late notice. Norwell did not request an extension from the USPTO to file a response, nor did it retain patent counsel to respond.

c. Failure to Adhere to the Pre-Publication Review Requirements the License

Norwell counterclaims that HJF breached Section 11.20 of the License Agreement by publishing an abstract poster at the American Society of Clinical Oncology (ASCO) conference that included data from the GP2 clinical trial funded by Norwell. The poster abstracted trial results from the ongoing combined trial of GP2 and E75. In its brief, Norwell also argues that submission of the abstract for acceptance at the ASCO conference, with a copy being sent to Norwell and Apthera, was a publication violating section 11.20.

Norwell argues that Section 11.20 gives it authority to prevent publication of such GP2 data. In addition, Norwell argues that it was not provided 30 days notice before publication as required.

In May 18, 2010 Mr. Patel sent a copy of a proposed draft for an ASCO presentation to Messrs. Rothe and McWilliams "Re: OUR ASCO poster – Vaccine X" with comments. (R-167) Dr. Peoples' email referred to the draft being sent as "[h]ere is one of the items we discussed." (C-164)

Mr. Patel responded with questions about interpretation of the results. Norwell did not raise an objection to an ASCO presentation at that time or inclusion of GP2 data in a presentation. (C-164, 166; R-167)

Eight months later, in February 2011, Dr. Peoples submitted an abstract of the proposed poster presentation to ASCO. Dr. Peoples sent both Norwell and Apthera a copy of the abstract which contained the data from each of their peptides and the combined trial. (C-272)

Approximately two months later, on April 14, 2011, Mr. McWilliams sent Dr. Peoples a message acknowledging their discussion of Norwell's objection to publication of GP2 data. He stated that removing the data was the right thing to do and asked to be advised when Dr. Peoples reached a decision.

The following day Mr. Patel requested assistance from ASCO in removing the information from publication if it was not voluntarily withdrawn. Mr. Patel called ASCO and sent a follow-up email. Mr. Patel noted that he received "...a draft of the subject abstract that was provided to us by George Peoples on February 18." (R-167)

On April 18, 2011 in an exchange of messages, Mr. Patel notified Dr. Peoples of the "...drop dead

date deadline for removal of our data from the abstract is COB this Tuesday, 4/19/11, tomorrow." (R-167) Mr. Patel also instructed Dr. Peoples to "...not communicate with Apthera with regards to GP2...." (R-167)

Mr. Patel sent another message to a more senior person at ASCO that day reiterating Norwell's objections and advising ASCO that "[w]e were not notified that an abstract with our confidential data was being submitted to ASCO and that non-confidential data from our competitor would be included." (R-167)

On April 19, 2011 Mr. Patel also notified HJF of Norwell's objection to publication by Dr. Peoples and again notified Dr. Peoples to "[p]lease remove all of the confidential GP2 data from the abstract...." (R-167)

A month later on May 18, 2011, Mr. Patel contacted ASCO again to request that they drop the poster presentation if Dr. Sears, the presenter of the Abstract, or Dr. Peoples did not withdraw it. (R-167) ASCO did not agree to drop the poster presentation or to delete GP2 data from it.

Ultimately the following change in the poster presentation was made by

Dr. Peoples who notified Norwell on April 18 that:

> "Although I'm under no obligation to do so, as my last act of goodwill toward Norwell, I have petitioned ASCO to remove the GP2 name and sequence information from the abstract thus preventing any unwanted and identifiable public disclosures. However, the blinded data will remain in the abstract to support the conclusions of the accepted abstract per their requirements/guidelines." (R-167)

In June 2011, the Poster presentation was made with the modification described by Dr. Peoples.

Section 11.20 provides:

> "Prior to a Party's submission for publication or presentation technical developments and/or research findings related to the Patent Rights licensed hereunder, the publishing or presenting Party shall provide the other Party with at least thirty (30) days for review and comment upon the manuscript or other material proposed for publication. In addition, if requested by the other Party, the publishing or presenting Party will withhold such submission for publication or presentation for an additional thirty (30) days to allow for filing a patent application or taking such measures, as the Party deems appropriate to establish and preserve its proprietary rights in the information in the manuscript or presentation." (C-59)

Section 11.20 required that Norwell be given 30 days notice prior to submission for publication or presentation and Dr. Peoples did not provide 30 days notice to Norwell before submitting the abstract to ASCO for review. He notified Norwell and Apthera shortly after submission, attaching the abstract to each.

Norwell did not receive the requisite number of days notice before submission; however, it had more than 60 days notice prior to the scientific presentation at the ASCO conference in June 2011.

The purpose of § 11.20 is to allow Norwell, the licensee, to review the information to be published and to make a determination whether any patent or other intellectual property protection is needed. Upon such review and determination, Norwell can also request another 30 days in which to protect such rights, if any. The wording of § 11.20 suggests that as long as Norwell was first given the opportunity to protect its intellectual property rights in the presentation, such a presentation could be made if Norwell chose not to utilize the recourse available to it under § 11.20.

The evidence is persuasive, based upon the timeline above, that Norwell did not timely exercise its contractual rights or timely register an objection. Norwell has failed to produce evidence that if it had been given the 30 day notice prior to the abstract being submitted for review it would have taken steps contemplated by the 30 day notice window for intellectual property protection or that it was damaged by an inability to do so. The Panel finds that Norwell was not given 30 days notice as required prior to the abstract being submitted to ASCO. Norwell did, however, have more than 30 days notice prior to publication in June 2011 at the ASCO conference. The Panel also finds that Norwell failed to seek an extension of time, or patent protection or injunctive relief to protect its intellectual property. Finally, the Panel finds that Norwell has not established any amount of monetary damages from either the failure to receive the 30 day notice required under the 2009 License or the subsequent publication of the GP2 data.

d. Failure to Provide All Clinical Data and FDA Correspondence on a Timely Basis

Section 5.6 of the License Agreement requires that HJF "shall make available to the Licensee all preclinical, manufacturing, and clinical data and information in its possession related to the Patent Rights

licensed hereunder." Norwell complains that HJF did not provide all of the clinical data and information, including the Case Report Forms (CRFs), generated during the GP2 trial despite Norwell's requests for the material. HJF dismisses Norwell's argument about the CRFs, stating that the CRFs are not data; rather, they contain data. Regardless of whether the CRFs constitute "data" in and of themselves, they are included within a reasonable interpretation of "information" as it is used in the contract. Furthermore, these data and materials were necessary according to Norwell to demonstrate to potential investors that Norwell had access to and the ability to use all the clinical trial information available pertaining to GP2. Norwell points out that the CRFs were needed if it was to have auditable data to present to potential pharmaceutical partners or to the FDA in support of Norwell's own IND for GP2. Norwell's position with respect to the need for the CRFs and auditable data was supported by the testimony of both Dr. Thompson and Dr. Menander.

Norwell similarly maintains that it did not receive all FDA correspondence pertaining to the GP2 IND and clinical trial, despite repeated requests for all of the correspondence.

Dr. Mark Scher, the individual at HJF with operational responsibility over the License Agreements and who was Norwell's principal point of contact at HJF, testified that reference in the License Agreement to "in its possession" meant material physically located at HJF's headquarters in Bethesda, Maryland. The Panel does not accept Dr. Scher's narrow interpretation of the meaning of "possession." Wherever the data may have been physically (or digitally) stored, if HJF had access to or control over the data, then the data was in its possession within the meaning of the contract. Moreover, Dr. Scher claimed that until discovery commenced in this arbitration he was unaware that an HJF employee, Laura Ferrise, whose office is located at HJF headquarters, had all of the clinical trial data requested by Norwell on her HJF laptop and that HJF actually had all the referenced data in its possession. In short, all of the clinical trial related data requested by Norwell was in HJF's possession or control and no reason was offered by HJF as to why all of the data, including CRFs, could not have been provided to Norwell as requested.

HJF responds that while Norwell did not receive all of the data it requested, it had access to *most* of the data and, according to HFJ's expert, Mr. Berneman, it had enough of the data to allow it to arrange a pre-IND meeting with the FDA. The problem with HJF's argument is that Norwell was entitled to *all* of the data, not just some of the data. Dr. Peoples, who knew what data Norwell did and did not have access to and what it would need for its own IND, apparently believed Norwell did not have everything it needed for the IND, because he demanded $500,000 to provide Norwell with the IND, the FDA correspondence, and the ACCESS Database containing all the GP2 data. According to Dr. Peoples the foregoing were needed by Norwell, "to go forward." (Tr. 10/17/13, 276)

With respect to the FDA correspondence, HJF contends that Norwell either had all the FDA material or it was made available to Norwell at Dr. Peoples' office, but that Norwell failed to copy the material. Norwell says that Dr. Peoples, who maintained a complete set of the FDA correspondence, gave various excuses and dragged his feet about allowing Norwell to copy the correspondence when it wanted to. According to Dr. Peoples, Norwell had 90% of the FDA correspondence through the reports that it routinely received. According to Norwell, it had 10% of the FDA correspondence.

Silvja Salai, an HJF employee, testified that all the FDA correspondence is maintained at Brooke Army Base. A number of HJF employees work at or in conjunction with the Brooke facility. Ms. Salai testified that she had all the FDA correspondence at least since she started working at HJF in June of 2009 and sent copies of the correspondence to persons at HJF headquarters. (Silvja Salai Depo 18-22, 31-36) Marianne Spevak, also an HJF employee, testified that HJF had copies of FDA correspondence at its headquarters (Marianne Spevak Depo 125:11-13). Ms. Salai also testified that Dr. Peoples instructed her to send the FDA correspondence from Brooke to HJF.

From the evidence presented the Panel does not believe there were any limitations on HJF's ability to provide FDA correspondence to Norwell. As with the clinical trial data, it appears that HJF had possession of most, if not all, of the FDA correspondence and easily could have provided Norwell with all the FDA correspondence, either directly or with a simple request to Brooke. The only reason Norwell did not obtain all of the FDA correspondence is because Dr. Scher repeatedly and wrongly told Norwell that

HJF "does not possess any FDA correspondence relating to GP2." (R-130) Apparently, Dr. Scher never asked anyone at HJF whether it had the correspondence before he made his inaccurate statements.

HJF complains that both parties were required under the License Agreement to provide the other with FDA correspondence and that Norwell did not provide HJF with copies of the FDA correspondence that Norwell had in its possession. Norwell's failure to furnish copies of FDA correspondence to HJF is, at most, an immaterial breach of the License Agreement with no damage asserted by HJF

HJF claims that even if Norwell did not receive the data and FDA correspondence the Panel finds it was entitled to, it suffered no damage as a result; however, Norwell strongly contests HJF's assertion. Section 4.2 of the 2009 License Agreement requires Norwell to raise $3,000,000 within 36 months (per the amendment to the License Agreement) whether by debt, equity or grant. To meet the bulk of its contractual obligation under §4.2, Norwell applied for a $2.5 million grant from the Texas Emerging Technology Fund (ETF), a Texas state entity that provides outright grants to start-up companies like Norwell in order to bring technology-based employers to Texas. The ETF process is a back-and-forth process between the applicant and ETF. A successful applicant may be asked to refine its application a number of times before it receives final approval and funding. Norwell's uncontradicted evidence showed that once approved by the Advisory Committee, subsequent approval by the Governor's office is forthcoming almost without exception. On April 15, 2011, the Governor's Advisory Committee approved Norwell's grant application for $2.5 million and advanced the application to the Governor's office for final due diligence.

The approval of Norwell's application was side-tracked, however, by Governor Perry's presidential campaign bid and, in September 2011 a new Advisory Committee was appointed, which re-reviewed Norwell's application. This time the Advisory Committee declined to recommend Norwell's application, as then submitted, to the Governor's office. In an April 2012 email from Bob Prochnow, an ETF official (R-69), the committee informed Norwell of four issues it required Norwell to satisfactorily address if it was to obtain funding approval:

Issues one and two revolved around the Advisory Committee's concern over Dr. Peoples' profound conflicts of interest due to his promotional and financial involvement with several competing peptides licensed to competing companies. According to Dr. Thompson, who was present during the Advisory Committee's discussions regarding the Norwell application, to satisfactorily address these concerns Norwell needed to distance itself from Dr. Peoples. Specifically, Norwell needed to show that Dr. Peoples no longer controlled GP2 or the GP2 clinical trial. To do this, Norwell had to demonstrate that it could continue the GP2 clinical trial without Dr. Peoples. This meant that Dr. Peoples would have to transfer the GP2 IND to Norwell, together with the underlying data and FDA correspondence. As indicated above, when Norwell made its request, Dr. Peoples refused to accommodate the requested transfer unless Norwell paid $500,000 to him, personally. Given Dr. Peoples' demand, Norwell's alternative, its so-called "Plan B," was to obtain its own IND from the FDA, utilizing the clinical trial data and FDA correspondence to which it was entitled under the License Agreement.

Dr. Thompson testified under subpoena and for no compensation as an expert witness for Norwell. In addition to her integral position in the Texas ETF apparatus, Dr. Thompson is a Ph.D statistician with extensive FDA regulatory experience in biotechnology and the pharmaceutical industry. Her experience includes obtaining and managing FDA INDs. According to Dr. Thompson, if Norwell had all the clinical trial data and FDA correspondence in its possession at the time of its IND application, i.e., a complete set of auditable data, there was no reason Norwell could not have obtained its own IND from the FDA and, thus, establish its independence from Dr. Peoples.

As indicated above, HJF contends that because Norwell assertedly had access to most of the data it needed, it should have had a "pre-IND meeting" with the FDA to see what additional information was needed to support its IND, but failed to do so. HJF also cites Dr. Menander's testimony to suggest that it would have taken Norwell two years to put together its own IND package. According to HJF, this demonstrates that it would have been too expensive for Norwell to have pursued Plan B. A difficulty with HJF's argument is that Norwell is under no obligation, contractual or otherwise, to pursue any specific strategy, including the one suggested by HJF after the fact, to obtain an IND. Both Drs.

Menander and Thompson testified that Norwell needed auditable data that it lacked to obtain its own IND from the FDA. Dr. Peoples also testified that what Norwell needed to go forward with the IND was the complete set of data that he offered to sell to Norwell for hundreds of thousands of dollars. Contrary to HJF's characterization of Dr. Menander's testimony, she was very clear in her testimony that it could take two years to put together the IND package *without* all the existing GP2 data from Dr. Peoples. In summary, while Norwell could have sought a pre-IND meeting with the FDA, there is no evidence such a meeting would have made any difference in its predicament with the ETF and, in fact, it might have served only to delay matters further.

The third and fourth issues raised by the Advisory Committee required Norwell to show that investors "would be interested" in investing in Norwell and that the founders/officers of Norwell had a financial commitment to the company. Both Dr. Thompson and Mr. Patel testified that concerns three and four would have been resolved simply by obtaining a) a statement of interest in further funding from an outside source (which Mr. Patel testified without contradiction Norwell could get from an interested investor, Ken Hallock), and b) a commitment from Norwell's officers to put additional monies into the company (which Mr. Patel testified, again without contradiction, Norwell officers McWilliams, Rothe and Patel would do).

Of the witnesses who testified in these proceedings, Dr. Thompson was uniquely qualified to testify about the ETF process and had personal knowledge of Norwell's ETF grant application. She testified that in her opinion, based on her years of experience with the ETF grant funding process, including her position on the Governor's Advisory Committee, and her personal involvement with Norwell's grant application, the company would ultimately have gotten the requested EFT funding. Dr. Thompson could only remember one instance out of more than 70 approved grant applications where a grant applicant had reached a comparable stage in the ETF process and did not receive funding. It was Dr. Thompson's opinion that the issues in the Prochnow email (R-69) did not represent significant hurdles to Norwell's application. A majority of the Panel accepts Dr. Thompson's testimony and finds

that it was a virtual certainty that Norwell had reached the stage in the ETF grant process in which, with the data and its own IND, it would have received the $2.5 million grant from ETF.

On the other hand, lacking possession of the data and FDA correspondence from HJF, there was no way for Norwell to demonstrate to the ETF that it would be able to successfully pursue the IND on its own and gain control of the clinical trial. To add to Norwell's difficulties, HJF's failure to provide the data and correspondence that Norwell requested was coupled with HJF's wrongful termination of Norwell's 2009 license rights on March 16, 2012, which occurred more than a month before receipt of Prochnow's communication on April 26, 2012. HJF's termination of Norwell's rights occurred despite Dr. Scher's and HJF's knowledge that Norwell had previously been approved for a $2.5 million ETF grant and was still eligible for ETF funding. (See, e.g., R-62) With respect to the funding requirements contained in §§4.2 of both the 2009 and 2010 License Agreements, termination of the licenses by HJF - which left Norwell with no rights whatsoever to GP2 – constituted a total and fundamental breach that made it impossible for Norwell to secure the $2,500,000 of ETF funding or to otherwise fulfill its obligations under §4.2.

The Panel finds that HJF materially breached the License Agreement by its failure to provide Norwell with all of the clinical data and FDA correspondence in its possession. This breach of contract by HJF excused Norwell from performance under the License Agreement, including most significantly for our purposes here, its obligation to pay the installment due for its $3,000,000 Clinical Trial Financial Support obligation. HJF's termination of the License Agreement (C-355; C-380), predicated on non-payment of the quarterly installment of the Clinical Trial Financial Support and other payments, therefore, was wrongful. In addition, the failure to provide the clinical data and FDA correspondence had the further effect of preventing Norwell from obtaining its own IND before HJF terminated the License Agreement. HJF's wrongful conduct not only made it impossible for Norwell to conclude its dealings with the ETF to obtain funding, it also precluded Norwell from approaching any other investor with respect to GP2 – Norwell's only product – since without the License Agreement it no longer had any rights to GP2. The lack of data and FDA correspondence and, hence, the means to obtain an

"independent" IND, combined with Norwell's wrongful loss of its license rights, made it impossible for Norwell to obtain the ETF funding that would have largely satisfied Norwell's obligations specified under §§4.2 of both the 2009 and 2010 License Agreements.

In summary, HJF's termination of both the 2009 and 2010 License Agreements was not justified and constituted a wrongful termination of those contracts. A majority of the Panel finds that Norwell has established that HJF's actions in wrongfully terminating the contracts prevented Norwell from complying with §4.2 of the License Agreements and was the proximate and direct cause of damage to Norwell in the amount of $2,500,000. Section 11.3 of the 2009 license and § 10.3 of the 2010 license provide that HJF's "aggregate liability for all damages of any kind relating to this Agreement or its subject matter shall not exceed the amount paid by Licensee to the Foundation under this Agreement." Respondent's exhibit R-14 shows that the amount paid by Norwell to HJF pursuant to the 2009 and 2010 licenses totals $2,139,265. The accuracy of the foregoing figure was not disputed by HJF. Accordingly, the Panel will award Norwell damages of $2,139,265.

Norwell also seeks delay damages of $18 million. Norwell's proof of the amount of its claimed delay damages, based on comparisons with other start-up companies, is speculative. Moreover, the cap on damages under §§ 11.3 and 10.3 of the License Agreements would prevent the award of the additional damages sought by Norwell. Accordingly, delay damages are not awarded to Norwell.

e. Termination of GP2 Clinical Trial Enrollment

On January 20, 2014, counsel for Norwell requested the AAA administrator, Ms. Donyale Brazier, to inform the Panel that in December 2013 the enrollment of GP2 patients had been terminated. The Panel requested informal responses from both parties with respect to Norwell's inquiry, which it received on January 22 and 23, 2014 respectively.

On January 30, 2014, the Panel issued a Post-Hearing Order reopening the record of the proceedings for the limited purpose of obtaining HJF's response to specific questions raised by the Panel. HJF provided its response on February 6, 2014.

Norwell was invited to provide a reply, which it submitted to the Panel on February 12, 2014.

In its letter dated January 22, 2014, counsel for Norwell alleges that HJF/Peoples stopped the enrollment of GP2 patients improperly and prematurely, based on reaching a total number of approximately 180 patients, but without any statistical significance, to the detriment of Norwell, and in direct contradiction with the email correspondence dated May 7, 2009 (R-23) between Dr. Peoples and Eric Rothe.

In its letter dated January 23, 2014, counsel for HJF asserts that there have been no new developments, and that the enrollment was stopped in accordance with the testimony of both Dr. Peoples and Dr. Beth Mittendorf ("Mittendorf"), who both testified that they expected that the target numbers would be reached and the patient enrollment stopped by the end of 2013, citing Tr. 10/16/13 92:20-22, 96:8-19, 103:17-104:17 (Mittendorf); and Tr. 10/15/13 595:5-20 (Peoples).

In a Declaration submitted as an attachment to the February 6, 2014 letter from HJF counsel, Dr. Mittendorf, in response to the specific questions raised by the Panel, asserts that the enrollment of patients was "completed", as "the total number of events that must be observed to achieve the specified power is 33", quoting Section 1.2 of the Statistical Analysis Plan applicable to the GP2 trial. (C-310 at HJF013084).

Thus, Dr. Mittendorf argues, the primary statistical analysis is event driven, meaning it is based on the number of recurrences rather than the number of patients enrolled. Mittendorf Declaration Para. 6.

Dr. Mittendorf further explains that at the end of 2013, there were 180 patients enrolled to the GP2 trial using the 1:1 control group (vaccinated = 89, control = 91) and 302 patients enrolled using the extended control group (vaccinated = 89, control = 213) with 122 additional control patients available to increase the power of the analysis. Mittendorf Declaration Para. 8.

Dr. Mittendorf reports that the number of breast cancer recurrences at the end of 2013 (n=34) achieved the pre-specified number of events (n=33). Mittendorf Declaration Para. 7. Dr. Mittendorf does not specify whether this number of recurrences was achieved using the 1:1 control group, or whether this number is based on the extended control group. Based on the information made available to the Panel by HJF and in view of Mittendorf's extensive explanation of the acceptability of using the combined control

group, the Panel finds that this number of recurrences (n=34) is based on the extended control group for a total of 302 patients enrolled in the (extended) GP2 trial.

Dr. Mittendorf's Declaration also fails to indicate the number of recurrences in the vaccinated group versus the (extended) control group, to determine whether the results could be interpreted as statistically significant at this stage.

With regard to this issue, Dr. Peoples testified that it was likely that he would stop enrollment by the end of the calendar year (2013), denying that one of the enrollment criteria is that the results are statistically significant. "That's not why you end a trial. You end a trial based on a prescribed number of patients." And because "[t]his has a two-year follow-up period. So these patients will be followed in real time, and so there are so many recurrences, you don't stop based on the recurrence number. You stop based on the enrollment number." Asked what that enrollment number is, Dr. Peoples testified, "300 patients in the AE37 arm, 200 patients in the GP2 arm.", correcting himself, saying "Well, I slightly misspoke. It's 180 in the GP2 arm, but there's going to be over 200." Tr. 10/18/13, 61:7-62:8.

The Panel notes that at no point did Dr. Peoples testify about the pre-specified number of recurrences as explained in the Mittendorf Declaration. During the same session, Dr. Peoples was asked, "To date, meaning as of today, do you know if the current results that you have right now are statistically significant?" Dr. Peoples answered, "They are not currently statistically significant." Tr. 10/18/13, 63:10-14.

The January 2011 Statistical Analysis Plan ("SAP"), which pursuant to its heading applies to the AE37 trial "OR" the GP2 trial, assumes that the sample size in terms of the number of enrolled patients is 300. Section 1.2 of the SAP, entitled "Sample Size Determination," provides in relevant part as follows:

> "We assume that it will take 36 months to accrue 300 subjects (100 subjects/year) and another 24 months of follow-up after enrollment of the last subject to achieve the targeted number of DFS [=Disease Free Survival] events (n=33 recurrences) and an additional 36 months (60 months in total) to report the number of deaths." (C-310, at HJF013084)

The third paragraph of Section 1.5.6 of the SAP entitled "Planned Analyses," reads in pertinent part:

"... the current plan is to enroll only 200 subjects in the GP2 arms; therefore, the [planned] analyses above requiring 300 subjects will not apply." (C-310 at HJF013090)

The question arises whether the number of 300 (or 200) subjects includes the extended control group or whether this number applies to each arm. Dr. Peoples testified that the AE37 group consists of 300 patients (see, Tr. 10/18/13, 61:7-62:8), which would appear to confirm that this provision in the SAP refers to each arm separately. This conclusion would also correspond with the expected number of recurrences based on Dr. Peoples' experience with the completed E75 clinical trial, where the number of recurrences approximated 10.5%. See Mittendorf, Tr. 10/16/2013, 108:2-4; Patel Declaration, Para. 9(b)(ii). Indeed, 300 patients for each arm of the trial, with a targeted number of 33 recurrences, would also translate into the slightly higher figure of 11% recurrences. If the number of recurrences is only based on 200 enrolled patients, however, the targeted number of recurrences of 33 would appear to be high, as this would translate into a percentage of 16.5%.

On the other hand, the last paragraph of Section 1.4 of the SAP mentions that the control groups can be combined in certain circumstances, in which case "the randomization will switch to a 2:1 [sic] scheme (vaccine:control) for both the GP2 and AE37 arms of the trial." (C-310, at HJF013085)

Enlargement of the control group, while it assertedly enhances the reliability of the control group data, does not translate into a linear increase of the statistical significance of the total number of patients enrolled.

It is not enough to simply rely on the number of recurrences as an indication of when to stop patient enrollment, especially if such number (as here) includes recurrences in the extended control group, as the latter only provides more reliable data on that side of the equation. Nor is it sufficient to rely simply on the number of patients to know when patient enrollment can be stopped, as the statistical relevance is determined by having achieved a sufficient differential between the respective numbers of DFS events among the vaccinated and control groups. This is illustrated by Section 1.2 of the January 2011 SAP which combines in the trial a number of patients enrolled and a targeted number of recurrences.

Mr. Patel observes in his Declaration of February 12, 2014, that "the 33 total recurrences is not a stopping rule for enrollment. It is instead a calculation factor for sizing the trial, located in the "sample size" section of the protocol and is irrelevant." Patel Declaration Para. 9.b.ii.

The Panel is unable to determine from the information provided by HJF in response to the Panel's post-hearing inquiry that the requirements of the Sample Size Determination set forth in Section 1.2 of the January 2011 SAP, whether or not it was intended as a stopping rule, had been met by the end of 2013.

Even if termination of enrollment at the end of 2013 was consistent with the January 2011 SAP, Norwell alleges that the 2011 SAP could not be amended in a manner that would permit termination of GP2 patient enrollment at the end of 2013 in violation of the agreement that is outlined in the May 7, 2009 email exchange between Peoples and Rothe. (R-23) The 2009 email exchange requires the continuation of the clinical trial of GP2 until the ongoing analysis of the trial statistics justifies termination of patient enrollment.

Norwell's allegation raises the question of whether HJF was in any way obligated towards Norwell to comply with the email exchange of May 7, 2009. In order to answer this question, the Panel needs to determine whether the email of May 7, 2009 (R-23) constitutes an enforceable agreement between HJF and Norwell. As Norwell's License Agreement is with HJF, to which Peoples as an individual is not a party, and as this email is an exchange between Dr. Peoples and Mr. Rothe, who was the President of Norwell during that time, this determination depends in part on the position of Dr. Peoples versus HJF.

Exhibit R-23 consists of two email messages, one from Peoples to Rothe at 3:22 PM, and the other from Rothe to Peoples at 4:11 PM on May 7, 2009. The body of the first email (with a copy to Dr. Scher) reads in its entirety as follows:

> "Eric
> In follow-up to our phone conversation, we'll base everything off an enrollment target of 180 patients understanding that we may need to enroll more pts as determined by the statistics. As you know the trial is written for 180-300 patients depending on the analysis. Instead of doing a straight $15k/pt cost which could get expensive if we go substantially over the 180 pts, we'll agree to accept $3M for the entire trial.

> As you know, we have already completed approximately 1/3 of these patients. By signing this agreement, you'll be agreeing to pay for these patients as a proportion of the total; however, we will not require $1M upfront but accept your paying the $3M on a straight quarterly payment schedule of $250k/quarter. If the trial is terminated the actual cost will be based on the proportion of the 180 pts enrolled at that time.
> Acceptable?
> Thanks,
> George"

The body of the second email, addressed to Peoples, with copies to Scher, Lentz and McWilliams reads in its entirety as follows:

"Yes, acceptable."

The Panel need not decide whether Peoples had actual authority to bind HJF, if it is proven to its satisfaction that Peoples had the apparent authority to bind HJF. Authority conferred upon the agent by the principal can take two forms: actual or apparent. The court in *Progressive Casualty Ins. Co. v. Ehrhardt*, 69 Md. App. 431 (1986) held:

> "Actual authority is that which is actually granted, and it may be express or implied. Apparent, or, as it is also called, ostensible authority, on the other hand, is that authority which, though not actually granted, the principal knowingly permits the agent to exercise or which himself holds out as possessing." 69 Md. App. At 440.

Maryland has adopted the Restatement (Second) of Agency, §267 (1958) in determining the existence of an apparent agency relationship. Apparent authority results from certain acts or manifestations by the alleged principal to a third party leading the third party to believe that an agent had the authority to act. *Dickerson v. Longoria*, 414 Md. 419, 442, 995 A.2d 721, 735 (2010). Applying this rule, Norwell, seeking to recover on the theory of apparent agency, bears the burden to show that appearances created by Dr. Scher, the HJF representative in charge of the license negotiations with Norwell, led Norwell to believe that Peoples was HJF's agent. See *JAI Medical Systems Managed Care Organization, Inc. v. Bradford*, 209 Md. App. 68, 57 A.3d 1068 (2012).

The Panel finds that Norwell has met this burden: Dr. Scher was aware that Dr. Peoples was negotiating terms relating to Norwell's paying for the GP2 clinical trial. He was copied on several emails between Peoples and Norwell, including the May 7, 2009 email. It is also clear that Peoples and Scher

were in regular contact with each other and kept each other abreast of the progress of the negotiations. See, *e.g.* email exchange between Peoples and Rothe dated April 16, 2008 (R-22), in which Dr. Peoples tells Mr. Rothe, "I know that you and Mark have been negotiating license terms, but I haven't heard the final outcome. That's between you guys. As for the science, here's the deal..." Importantly, Dr. Scher chose not to react in any way to either Dr. Peoples' email of May 7, 2009 or to Mr. Rothe's response on the same day. Dr. Scher testified he saw "no need" to get involved with Dr. Peoples' discussion of the science as long as HJF would receive its $3 million clinical trial support. In Dr. Scher's view "the science and the dollars associated with the science are one and the same." Tr. 10/15/2013, 403:21-404:16; 420:3-425:11; 435:7-20. Dr. Scher's silence in the face of commitments made by Dr. Peoples relating to critical aspects of the clinical trials that were to generate the data that were at the center of the sponsored research underlying the license, is behavior that can reasonably be interpreted as acquiescence. As a result, Dr. Peoples had the actual or at least the apparent authority to bind HJF with respect to the "science discussions between Norwell and Dr. Peoples." *Id.*, 420:5.

A great deal of the confusion was caused by the not entirely successful attempt to combine a License Agreement and aspects of a sponsored research agreement into a single document, -- something that caused Rothe considerable discomfort. In Rothe's experience, this was very unusual. Tr. 10/21/13, 19:1-5. The result was that portions of what would normally be found in a separate sponsored research agreement were either lacking completely or contained in separate correspondence.

The License Agreement (R-17) states that it has an "Effective Date" of April 24, 2009. Arguably, agreements contained in email correspondence dated prior to the Effective Date are erased by the integration clause contained in § 11.19 of the Primary License. However, § 11.19 cannot be deemed to include an agreement entered into at a date subsequent to the Effective Date, such as the agreement contained in the email exchange dated May 7, 2009 (R-23). Norwell signed the License Agreement after the May 7th date, and it did so with retroactive effect, while the email contains no provision that it too would have retroactive effect.

By the express language of the emails of May 7, 2009, this is an offer and acceptance of an agreement, entered into by Peoples (on behalf of HJF) and Rothe on behalf of Norwell. This agreement establishes two important elements: first, although this agreement "switches" from the original deal that was based entirely on a cost per patient basis to an overall $3M cost for the entire trial, the original concept of a per patient cost ("the actual cost") is still preserved if the trial is terminated, and will be based on the proportion of the 180 patients enrolled at the time of termination.

Second, although the enrollment target was 180 patients, there is an understanding between the parties that more patients may need to be enrolled "*as determined by the statistics*." [Emphasis added] The Panel finds that this constitutes an agreement that when to stop patient enrollment is a function of statistical relevance, and that enrollment would continue, up to 300 patients, until statistical relevance was achieved for a fixed payment obligation of $3 million.

As Mr. Patel points out in his Declaration, Antigen Express, using the same protocol as Norwell, had negotiated treatment of 330 patients for the AE37 arms (R-141, p.5 and R-146, at HJF012050), and Galena, which would have been using the same protocol as Norwell, had negotiated treatment of 180-300 patients for the GP2 arms with use of recurrence rates (not recurrence numbers) and statistical analysis as stopping rules for patient enrollment.

In summary, the Panel finds that Norwell was entitled to and did rely on the understanding set forth in the May 7, 2009 email exchange with HJF's agent, Dr. Peoples, and that the terms of the May 7, 2009 email exchange are binding upon HJF.

Given the current relationship of the parties and Dr. Peoples' stated unwillingness to work with Norwell (see, e.g., R-167), any attempt to require the parties to work together to restart and then continue the clinical trial at the existing trial sites, might only serve to lead to further discord and legal proceedings. Indeed, Norwell has indicated its intention to pursue the GP2 clinical trial on an independent basis. At the same time, since patient enrollment in the clinical trial has been terminated based on HJF's determination that the appropriate statistical stopping point for GP2 patient enrollment has been achieved, it is impractical that HJF would restart enrollment of patients in the GP2 clinical trial.

Since we have determined that the enrollment requirements of the May 7, 2009 agreement have not been met, and since HJF has not notified the Panel that it would do so after receiving the objection of Norwell, it would be unfair to require Norwell to continue to pay HJF under the License Agreement to fund the GP2 clinical trial for further enrollment which may now be undertaken by Norwell. Therefore, Norwell will be relieved of its Clinical Trial Financial Support obligation under § 3.6 of the License Agreement and any unpaid delay fees under Section 17 of the First Amendment and Section 5 of the Second Amendment. Norwell will be free to pursue the GP2 clinical trial on an independent basis.

Due to the suspension of the License Agreement during the approximately 24 months that this arbitration has been pending, the Panel finds that certain adjustments regarding payments under §§ 3.3 (i), 3.4, 7.2 and 7.3 of the License Agreement and the exercise of HJF rights under Section 10.2 (c) of the License Agreement are required.

IV. Tort Claims

Norwell has asserted claims of fraud in the inducement and misappropriation of trade secrets.

a. Fraud in the Inducement

Norwell contends that HJF made false representations and promises, knowing that the representations were false, or without intending to perform in order to induce Norwell to enter into the License Agreements. Specifically, according to Norwell, HJF represented that (1) the 2009 license included sponsored research, (2) Norwell would receive all GP2 data, FDA correspondence, and the IND, (3) Norwell would be charged $15,000 per patient because a CTC assay was to be performed on all patients, and (4) the enrollment rate included 250 enrolled patients by the end of 2011. HJF's failure to adhere to these understandings, in Norwell's view, amounts to evidence of HJF's pre-existing intent to not honor its promises to Norwell.

To prevail on a claim for fraud in the inducement claim, Norwell must show: (1) a material representation of HJF was false, (2) the falsity of its representation was known to HJF or the misrepresentation was made with such reckless indifference to the truth as to impute knowledge to HJF, (3) the misrepresentation was made by HJF with the purpose of defrauding Norwell, (4) Norwell

justifiably relied on the misrepresentation, and (5) Norwell suffered damage directly resulting from the misrepresentation.

Assuming, solely for the sake of our analysis, that Norwell had established by clear and convincing evidence that all four of HJF's alleged representations were, in fact, false, there is no evidence in the record to suggest that the representations were made by HJF for the purpose of defrauding Norwell. Norwell lays its complaints of fraud largely at Dr. Scher's doorstep, for example, that Dr. Scher failed to explore the location of GP2 data and FDA correspondence, that he failed to appreciate the consequences of allowing the roles of Dr. Peoples and the Foundation to overlap during contractual negotiations, and that HJF, on Dr. Scher's watch, failed to deliver contractual performance meeting Norwell's expectations after the contracts were signed. But Norwell's criticisms of Dr. Scher and HJF, even if justified, do not on any level show the intent to defraud Norwell.

The Panel finds that Norwell has not proven its claim of fraud in the inducement and, accordingly, this claim is denied.

b. Misappropriation of Trade Secrets

Norwell asserts that HJF disclosed GP2 data to Norwell's competitors, by displaying the data at an ASCO meeting without the express or implied consent of Norwell in violation of the Maryland Uniform Trade Secrets Act (MUTSA).

In Maryland, a claim for misappropriation is statutorily prescribed by the Maryland Uniform Trade Secrets Act ("MUTSA"). Md. Code, Com. Law §§ 11-1201 – 11-1209. In pertinent part, the MUTSA defines misappropriation as the "[d]isclosure or use of a trade secret of another without express or implied consent by a person who: . . . knew or had reason to know that the person's knowledge of the trade secret was: . . . acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use . . . ." *Id.*, § 11-1201(c). In addition, a plaintiff asserting a claim for misappropriation must prove that it took reasonable measures to maintain its secrecy. *Id.*, § 11-1201(e)(2).

Norwell's misappropriation claim rests on the assertion that HJF's alleged publication of GP2 Data violated duties imposed by the Non-Disclosure Agreement ("NDA") (R-262) between the parties

and by § 11.20 of the 2009 license. Neither of these agreements, however, prohibits HJF's disclosure or use of GP2 data in the manner asserted by Norwell.

The confidentiality duties in the NDA are limited to confidential information that is disclosed to one of the parties by the other: "The Receiving Party shall maintain in confidence all Confidential Information disclosed to it by the Disclosing Party . . . ." (*See* NDA, § 5.) But Norwell did not disclose GP2 data to the Foundation. Neither does § 11.20, the publication provision of the 2009 Agreement, prohibit disclosure of the GP2 trial data by the Foundation. Rather, that provision requires only that the Foundation give Norwell 30-days advance notice of the disclosure so that Norwell might seek patent or other protection of the data. (*See* 2009 Agreement, § 11.20.)

Under Maryland law, the party asserting a misappropriation claim must demonstrate that some agreement restricted the defendant's disclosure of the subject information, which is not the case here under the NDA. Thus, even if the GP2 data published at the ASCO conference contained trade secrets, HJF's disclosure or use of that data (if any) is not a misappropriation under the MUTSA, because HJF was under no duty to maintain the secrecy of GP2 data and, in fact, such publication was anticipated by § 11.20.

The Panel finds that Norwell has not proven its claim of misappropriation of trade secrets and, accordingly, this claim is denied.

c. Charitable Immunity

HJF interposed a charitable immunity defense against Norwell's fraud claims. Norwell asserted in reply that HJF does not meet the definition of a charity under Maryland law or, alternatively, that HJF may not avail itself of charitable immunity against liability resulting from intentional torts committed by HJF.

In light of our ruling denying both of Norwell's fraud claims, there is no need to consider whether or not HJF meets the criteria for inclusion within the nearly impenetrable protective mantel of Maryland's charitable immunity doctrine.

Accordingly, WE AWARD as follows:

1) The termination by Claimant HJF of the Exclusive License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and Norwell, Inc., with an Effective Date of April 24, 2009, as amended by the May 7, 2009 email agreement between Dr. Peoples and Mr. Rothe, the first amendment to the Primary License, dated February 17, 2010, and the second amendment to the Primary License, dated September 24, 2010 (collectively the "2009 License Agreement"), is declared to be a wrongful termination and to be invalid, and the 2009 License Agreement is hereby reinstated in its entirety, except as otherwise specified in this Award.

2) Claimant HJF shall have all rights, privileges and obligations in accordance with the 2009 License, except as otherwise specified in this Award.

3) Respondent Norwell shall have all rights, privileges and obligations as the exclusive Licensee in accordance with the 2009 License Agreement, except as otherwise specified in this Award.

4) The termination by Claimant HJF of the License Agreement between The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. and The Brigham and Women's Hospital, Inc., and Norwell, Inc., with an Effective Date of February 16, 2010, ("2010 License Agreement"), was terminated without legal cause. Notwithstanding this, the 2010 License Agreement shall remain terminated and of no force or effect.

5) Respondent Norwell is relieved of all obligations under the terms and conditions of the 2010 License Agreement.

6) Claimant HJF shall pay to Respondent Norwell the sum of $2,139,265.00 (Two Million One Hundred Thirty Nine Thousand, Two Hundred Sixty Five and NO/100ths Dollars). This amount represents the amount of the $2,500,000 ETF funding, offset by the application of the cap on liability contained in § 11.3 of the 2009 License Agreement and § 10.3 of the 2010 License Agreement.

7) Interest shall accrue on the amount so awarded from the date of this Award until paid at the rate of 10% per annum (.8333% per month).

8) Respondent Norwell's Clinical Trial Financial Support obligation under § 3.6 or any other provision of the 2009 License Agreement is hereby declared fulfilled and satisfied to the date of this Award, and Respondent Norwell is relieved of any and all obligations to pay any future Clinical Trial Financial Support payments to Claimant HJF under § 3.6 or any other provision of the 2009 License Agreement.

9) Respondent Norwell is hereby relieved of any and all obligations to raise $3 million in funding, or any other amount, under § 4.2 or § 10.2 of the 2009 License Agreement.

10) The due date for all minimum royalty payments under § 3.3 (i) of the 2009 License Agreement shall be extended by 24 months. With respect to such royalties, if any, that were due and unpaid by Norwell as of the commencement of these proceedings or that became due prior to the date of this Award, when such royalties become due after the application of the foregoing 24 month extension, there shall be no interest, late payment, delay fee or other amount applied by HJF to the foregoing minimum royalty payments, unless any such payment is not made within the time frames that will apply as a result of the 24 month extension herein provided.

11) The due date for all maintenance royalty payments under § 3.4 of the 2009 License Agreement shall be extended by 24 months. With respect to such royalties, if any, that were due and unpaid by Norwell as of the commencement of these proceedings or that became due prior to the date of this Award, when such royalties become due after the application of the foregoing 24 month extension, there shall be no interest, late payment, delay fee or other amount applied by HJF to the foregoing maintenance royalty payments, unless any such payment is not made within the time frames that will apply as a result of the 24 month extension herein provided.

12) The due date for the reimbursement of Patent Expenses under §§ 7.2 and 7.3 of the 2009 License Agreement shall be extended by 24 months. With respect to such Patent Expenses, if any, that were due and unpaid by Norwell as of the commencement of these proceedings or that became due prior to the date of this Award, when such Patent Expenses become due after the application of the foregoing 24 month extension, there shall be no interest, late payment, delay fee or other amount applied by HJF to

the foregoing Patent Expenses payments, unless any such payment is not made within the time frames that will apply as a result of the 24 month extension herein provided.

13) Norwell shall not be obligated to pay any currently unpaid Delay Fees referenced in Section 17 of the First Amendment to the 2009 License Agreement or Section 5 of the Second Amendment to the 2009 License Agreement.

14) For a period of 24 months from the date of this Award, Claimant HJF shall not exercise the right under Section 10.2 (c) to either terminate the 2009 License Agreement or render the license non-exclusive.

15) The existing GP2 Case Report Forms (CRFs), summary and individual GP2 patient data, GP2 databases including GP2 data contained in the ACCESS Database or any other database or repository, and manufacturing data (collectively, "GP2 Data") shall, within 15 days from the date of this Award be provided by HJF to Respondent. All future GP2 Data shall be made available by HJF to Norwell on a timely basis.

16) Except to the extent already in Respondent Norwell's possession and not marked "confidential" or "attorneys eyes only," Claimant HJF shall, within 15 days from the date of this Award provide to Respondent Norwell a) all the FDA correspondence relating to (i) the GP2 clinical trial and (ii) the IND, and b) all GP2 Data, including without limitation the relevant ACCESS Database, in a format reasonably accessible by Norwell, except as the parties may otherwise mutually agree to in writing.

17) The FDA correspondence and GP2 Data provided to Respondent Norwell in accordance with the foregoing paragraph shall not be marked "confidential," "attorneys eyes only" or any similar designation that would in any way preclude or restrict Norwell's commercial exploitation of such materials.

18) Any designations of "Confidential" or "Attorneys Eyes Only" made by either party or such party's attorneys without proper authority to do so under the terms of the agreed Protective Order in effect in these proceedings shall be treated as withdrawn after the date of this Award. Any designations of "Confidential" or "Attorneys Eyes Only" made to material known to the receiving party without a duty

of confidentiality before receipt from the producing person, as evidenced by written records made prior to such receipt or disclosure, shall be treated as withdrawn after the date of this Award; provided, however that such written records shall be made available by the receiving party for inspection upon the request of the disclosing party.

Fees and Costs

Each party shall pay one-half of the filing and administrative fees and expenses paid to the AAA, and one-half of the fees and expenses paid to the AAA for the service of the Panel. Accordingly, the administrative filing and case service fees of the AAA, totaling $22,900.00, shall be borne equally. The fees and expenses of the arbitrators, totaling $328,844.53, shall be borne equally. The Panel has further determined that each party is to bear its own attorneys' fees.

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. Any claims or counterclaims made that have not been expressly addressed in this Award are DENIED.

This Award represents the majority opinion of the Panel.

This Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

SO ORDERED.

Dated: March 25, 2014

Arthur House
Panel Chair

Hon. Alice Sullivan (Ret.)
Panel Member

Eric van Ginkel
Panel Member

of confidentiality before receipt from the producing person, as evidenced by written records made prior to such receipt or disclosure, shall be treated as withdrawn after the date of this Award; provided, however that such written records shall be made available by the receiving party for inspection upon the request of the disclosing party.

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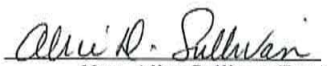
SO ORDERED.

Dated: _____

_____
Arthur House
Panel Chair



Hon. Alice Sullivan (Ret.)
Panel Member

_____
Eric van Ginkel
Panel Member

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This Award represents the majority opinion of the Panel.

This Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

SO ORDERED.

Dated: 3-25-14

Arthur House
Panel Chair

Hon. Alice Sullivan (Ret.)
Panel Member

Eric van Ginkel
Panel Member

Exhibit 10.7

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**") is made and entered into effective as of _____, 2020 (the "**Effective Date**"), by and between Snehal Patel (the "**Executive**") and Greenwich Lifesciences, Inc., a Delaware corporation (the "**Company**").

R E C I T A L S

Whereas, the parties wish to enter into an employment agreement between the Executive and the Company on the terms and conditions contained in this Agreement, which Agreement will supersede all prior agreements and understandings between the parties, oral or written, with respect to the subject matter of this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties hereby agree as follows:

1. Definition of Terms. The following capitalized terms used in this Agreement, but not otherwise defined herein, shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of an act of fraud, embezzlement or material dishonesty which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) Executive's willful misconduct that is materially injurious to the Company; (iv) a material breach of Executive's Confidentiality Agreement (as defined in Section 14 below) that is materially injurious to the Company; or (v) Executive's (1) material failure to perform his duties as an officer of the Company, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i) the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) obtains "beneficial ownership" (as defined in Rule 13d-3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("**Voting Stock**");

(ii) the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly fifty percent (50%) or more of the voting stock of the resulting entity or a parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii) there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, fifty percent (50%) or more of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "**Disability**" means a physical or mental disability, which prevents Executive from performing Executive's duties under this Agreement for a period of at least 120 consecutive days in any twelve month period or 150 non consecutive days in any twelve month period.

(d) "**Good Reason**" shall mean, without Executive's express written consent, any of the following: (i) a significant reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (iv) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 12 below. "Good Reason" shall not be deemed to exist, however, unless (1) Executive shall have given written notice to the Company specifying in reasonable detail the Company's acts or omissions that Executive alleges constitute "Good Reason" within ninety (90) days after the first occurrence of such circumstances and the Company shall have failed to cure any such act or omission within thirty (30) days of receipt of such written notice, and (2) Executive actually terminates employment within sixty (60) days following the expiration of the Company's cure period as set forth above. Otherwise, any claim of such circumstances as "Good Reason" shall be deemed irrevocably waived by Executive.

2. Duties and Scope of Position. During the Employment Term (as defined below), Executive will serve as Chief Executive Officer of the Company, reporting to the Chairman of the Company, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Employment Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing his investments, other business affairs or operations and other matters or serving on civic or charitable boards or committees, provided, however, that no such activities unduly interfere with the performance of his obligations under this Agreement, and further provided that Executive shall honor the non-competition and non-solicitation terms as per Section 15 below. During the Employment Term, Executive agrees to disclose to the Company those other companies of which he is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of the Effective Date and shall continue until December 31, 2021, unless earlier terminated in accordance with Section 9 hereof; provided, however, the term of Executive's employment hereunder shall be automatically extended for successive additional one (1) year periods unless the Executive or the Company delivers to the other party a written notice of its/his intent not to renew the Employment Term (as defined below), such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Employment Term. The period commencing as of the Effective Date and ending on December 31, 2021 or such later date to which the term of Executive's employment under the Agreement shall have been extended pursuant to this Section 3 is referred to herein as the "**Employment Term**" and the last day of the Employment Term is referred to herein as the "**Expiration Date**."

4. Base Compensation; Equity Grant. The Company shall pay to Executive a base compensation (the "**Base Compensation**") of $450,000 (four hundred fifty thousand dollars) per year payable in cash in accordance with the Company's standard payroll policies. In addition, each year during the Employment Term, Executive shall be reviewed for purposes of determining the appropriateness of increasing his Base Compensation hereunder. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4. Base Compensation will be pro-rated based on the number of days Executive was employed by the Company during any given year. In addition, Executive will be eligible for equity grants (the "**Equity Grant**") in the form of stock or options or other equivalents as mutually agreed upon by the Executive and the Board of Directors. As of the Effective Date, the Executive will continue to receive common stock grants per the vesting schedule as approved by the Board of Directors and listed on Attachment D, Stock Grant For Services, in the Board resolution dated September 30, 2019. The Executive may defer Base Compensation or Equity Grant at any time for any reason at his sole discretion.

5. Target Bonus. In addition to his Base Compensation and Equity Grant, Executive shall be given the opportunity to earn an annual bonus (the "**Bonus**") of up to 50% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "**Target Year**") to be mutually agreed upon by the Executive and the Board of Directors of the Company (the "**Board**") or its compensation committee (the "**Compensation Committee**"). Such performance milestones shall be established by December 31 of the prior year of the Target Year. The Bonus for a Target Year shall be paid before December 20 of the Target Year, even if the Executive is no longer employed by the Company at the time the Bonus is due. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 5, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365 (the "**Pro-Rated Bonus**"). The determinations of the Board or the Compensation Committee with respect to Bonuses will be final and binding. The Pro-Rated Bonus for the 2020 Target Year will be guaranteed and will be paid before December 20, 2020. If the Phase III clinical trial for GP2 is initiated before the end of 2020, an additional Bonus of $50,000 will be payable before the end of 2020. In 2021 and beyond the Bonus will be based on the achievement of mutually agreed operating goals for that year. To be clear, a 100% achievement of goals will result in a bonus payment of 50% of salary.

In addition to the above bonuses for 2020 and future Target Years, the Executive will be eligible for a Strategic Transaction Bonus. In the event the Company consummates any Strategic Transaction involving the Company and a counter party, regardless of the size of the transaction, the Company shall pay to the Executive a bonus payment of 5% of the Transaction Value (as defined below) paid or received by the Company in the transaction, payable by the Company (within 5 business days) to the Executive in the form of consideration received by the Company at the closing of the transaction. In the event any contingent consideration is agreed to be paid in connection with the Strategic Transaction (such as, for example, consideration payable upon the fulfillment of some condition or event which may or may not occur in the future), then such contingent consideration shall be included in the Transaction Value, and the Executive shall be paid his bonus with respect to that contingent consideration as and when it is received by the Company, even if contingent consideration is received after termination of employment or death of the Executive.

As used herein, Strategic "Transaction Value" shall include any of the following up to closing or thereafter: (i) cash paid in the transaction, (ii) the fair market value of any equity, equity-related, convertible, or debt securities issued, (iii) the fair market value of any other property transferred, (iv) balance sheet indebtedness assumed in connection with the transaction, and (v) all technology access/license fees, net royalty payments (total royalty payments paid to the Company minus total royalty payments paid by the Company to other parties) after launch of any product, commercialization or any other milestone bonus payments to the Company by a counter party or the converse up to closing or thereafter. If a closed Strategic Transaction is modified, extended, expanded or replaced with another transaction or a replacement transaction at any time, including after the first Strategic Transaction is terminated, then the Company shall make Bonus Payments based on the cumulative Transaction Value, which would include the Transaction Value, as defined above, from all transactions.

Any Bonus will be payable to the Executive if the performance milestones were achieved or Strategic Transactions were consummated (or "Earned") while the Executive was employed in any capacity (or if such Strategic Transaction was initiated by the Executive while employed and was consummated within 18 months after termination of the Executive). If any Bonus was Earned pursuant to this Agreement, including any Earned contingent or future payments related to a consummated Strategic Transaction, it will be payable even after the termination of the Executive for any cause, and in addition, will be payable to the Executive's estate or heirs upon his death.

6. Benefits. Executive shall participate in all employee welfare and benefit plans and shall receive such other fringe benefits as the Company offers to its senior executives and directors.

7. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in this Agreement, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement or otherwise. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Employment Term upon sixty (60) days' prior written notice for any reason or no reason. Executive may terminate the Employment Term for Good Reason by giving written notice of resignation for Good Reason in accordance with the definition thereof set forth in Section 1(d) above. Termination by Executive pursuant to this Section 7(b) shall be without prejudice to any right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement or otherwise.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in this Agreement and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement or otherwise, Executive's employment shall terminate automatically upon his death. Additionally, subject to the obligations of the Company in this Agreement and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement or otherwise, in the event Executive is unable to perform his duties as a result of Disability during the Employment Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

(d) Expiration of Employment Term. Subject to the obligations of the Company set forth in this Agreement and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity under this Agreement or otherwise, Executive's employment hereunder shall terminate automatically upon the Expiration Date.

8. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability, Termination by Executive without Good Reason or Expiration of the Term. In the event that Executive's employment hereunder is terminated during the Employment Term by the Company for Cause pursuant to Section 7(a), as a result of Executive's death or Disability pursuant to Section 7(c) or voluntarily by Executive without Good Reason pursuant to Section 7(b) or upon expiration of the Employment Period, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: (i) on the date of termination the Company shall pay to the Executive, a lump sum amount equal to (A) any portion of unpaid Base Compensation and Equity Grant then due for periods on or prior to the effective date of termination plus (B) any Bonus earned and not yet paid through the date of termination; (ii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; (iii) only in the event of Executive's death or Disability pursuant to Section 7(c) or in the event of the expiration of the Employment Period as a result of non-renewal by the Company in accordance with Section 3 hereof, on the date that the Bonus for the Target Year in which the date of termination occurs would have been payable had Executive remained employed by the Company through such payment date, payment of the Pro-Rated Bonus for the Target Year in which the date of termination occurs.

(b) Termination by Company Without Cause or by Executive For Good Reason. In the event that Executive's employment is terminated during the Employment Term by the Company without Cause pursuant to Section 7(a) or by Executive for Good Reason pursuant to Section 7(b), the Company shall compensate Executive as follows: (i) on the date of termination, the Company shall pay to the Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation and Equity Grant then due for periods on or prior to the effective date of termination plus (B) any Bonus earned and not yet paid through the date of termination; (ii) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and (iii) on the date that the Bonus for the Target Year in which the date of termination occurs would have been payable had Executive remained employed by the Company through such payment date, payment of the Pro-Rated Bonus for the Target Year in which the date of termination occurs; and (iv) provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company (the "**Release**") and the Release becomes effective (and no longer subject to revocation) within sixty (60) days following the date of termination, the Company shall (y) pay to the Executive the Severance Payment (as defined below), which Severance Payment shall be paid within five (5) business days following the date the Release becomes effective (and no longer subject to revocation) and (z) reimburse Executive's payment of COBRA premiums for twelve (12) months from the date of termination. As used herein, "**Severance Payment**" means an amount equal to twelve (12) months of Employee's Base Compensation and Equity Grant at the rate in effect as of the date of termination (or, in the case of a resignation for Good Reason due to a reduction in Base Salary, at the Base Salary rate in effect immediately prior to such reduction). In the event Executive's employment is terminated without Cause or for Good Reason and a Change of Control of the Company occurs within six (6) months of such termination, Executive also shall be entitled to the severance benefits set forth under Section 8(c). To the extent the review or revocation period applicable to the Release spans two of Executive's taxable years, the Severance Payment shall not be paid until the later taxable year. If the Company's reimbursement of Executive's payment of COBRA premiums pursuant to Section 10(b) or Section 10(c) would subject the Company to any tax or penalty under the Patient Protection and Affordable Care Act or Section 105(h) of the Code ("**Section 105(h)**"), Executive and the Company agree to work together in good faith to restructure such benefit.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 8(a) or Section 8(b) to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause or Executive for Good Reason at any time within six (6) months prior to the consummation of a Change of Control if, prior to or as of such termination, a Change of Control transaction was Pending (as defined in Section 8(d) below) at any time during such six (6)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i) on the date of termination (except as specified in clauses (D)), the Company shall pay to the Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation and Equity Grant then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination, (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination, and (D) on the date that the Bonus for the Target Year in which the date of termination occurs would have been payable had Executive remained employed by the Company through such payment date, payment of the Pro-Rated Bonus for the Target Year in which the date of termination occurs;

(ii) provided Executive executes the Release and the Release become effective (and no longer subject to revocation) within sixty (60) days following the date of termination (or, in the event case of a termination of Executive's employment without Cause or for Good Reason within the six (6) months prior to the consummation of a Change in Control, Executive either (y) previously executed the Release in accordance with Section 8(b)(ii) above or (z) subsequently executes the Release and the Release becomes effective (and no longer subject to revocation) within sixty (60) days following the Change in Control): (A) the Company shall pay to Executive a lump sum amount equal to twelve (12) months of Executive's Base Compensation and Equity Grant at the rate in effect as of the date of termination (or, in the case of a resignation for Good Reason due to a reduction in Base Salary, at the Base Salary rate in effect immediately prior to such reduction), which payment shall be made (1) in the case of such termination upon or following the Change of Control, within five (5) business days following the date that the Release becomes effective (and no longer subject to revocation) or (2) in the case of such termination prior to a Change of Control, immediately upon the consummation of the Change of Control (or, if the Release was not previously executed in accordance with Section 8(b)(ii) above, within five (5) business days following the date that the Release becomes effective (and no longer subject to revocation)); and (B) the Company shall reimburse Executive for the COBRA premiums he pays to maintain health insurance coverage for six (6) months following the date of termination;

(iii) notwithstanding any provision of any stock incentive plan, stock option agreement, realization bonus, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending (as defined in Section 8(d) below) but in no event beyond expiration of the original term of the award or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv) Severance benefits under this Section 10(c) and Section 10(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

(d) Definition of "Pending." For purposes of Section 10(c), a Change of Control transaction shall be deemed to be '**Pending**" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; or (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction.

(e) If Executive's employment terminates for any reason, Executive shall have no obligation to seek other employment and there shall be no setoff against amounts due to him under this Agreement for income or benefits from any subsequent employment.

9. Indemnification. The Company agrees to indemnify and hold harmless Executive, to the fullest extent permitted by the laws of the State of Delaware and applicable federal law in effect on the date hereof, or as such laws may be amended to increase the scope of such permitted indemnification, against any and all Losses if Executive was or is or becomes a party to or participant in, or is threatened to be made a party to or participant in, any Claim by reason of or arising in part out of an Indemnifiable Event, including, without limitation, Claims brought by or in the right of the Company, Claims brought by third parties, and Claims in which Executive is solely a witness. For purposes of this section, "**Claim**" means any proceeding, threatened or contemplated civil, criminal, administrative or arbitration action, suit or proceeding and any appeal therein and any inquiry or investigation which could lead to such action, suit or proceeding. "Indemnifiable Event" means any event or occurrence, whether occurring before, on or after the effective date of this Agreement, related to the fact that Executive was a director, officer, employee or agent of the Company or by reason of an action or inaction by Company in any such capacity whether or not serving in such capacity at the time any Loss is incurred for which indemnification can be provided under this Agreement. "Losses" means any and all damages, losses, liabilities, judgments, fines, penalties (whether civil, criminal or other), ERISA excise taxes, amounts paid or payable in settlement, including any interest, assessments, reasonable expenses, including attorney's fees, experts' fees, court costs, transcript costs, travel expenses, printing, duplication and binding costs, and telephone charges, and all other charges paid or payable in connection with investigating, defending, being a witness in or participating (including on appeal), or preparing to defend, be a witness or participate in, any Claim. The Company further agrees to maintain a directors and officers liability insurance policy covering Executive in an amount, and on terms no less favorable to him than the coverage the Company provides other senior executives and directors.

10. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by operation of law or otherwise.

11. Notices. Notices and all other communications contemplated by this Agreement shall be in writing (including email) and shall be deemed to have been duly given when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

12. **Confidential Information.** Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Employment Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "**Confidential Information**"). "Confidential Information" does not include general skills and experience or information that is generally available to the public or in the Company's industry. Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except (a) in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information, (b) when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information or (c) such information is in the public domain through no fault of Executive. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession.

13. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Employment Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any entity that is directly competing with the products being developed by the Company, which in the case of GP2 would be any entity pursuing HER2/neu 3+ breast cancer products in the adjuvant/neoadjuvant setting that would be seeking to prevent the recurrence of breast cancer.

(b) Non-Solicitation. The Executive further agrees that during the Employment Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. The Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and the Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by the Executive of his covenants and agreements set forth herein. Accordingly, the Executive agrees and acknowledges that any such violation or threatened violation of this Section 13 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to obtain injunctive relief against the threatened breach of this Section 13 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

14. Employment Relationship. Executive's employment with the Company will be "at will," meaning that, subject to the Company's obligations set forth in Section 8, either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

15. Section 409A. It is intended that each installment of the payments provided hereunder constitute separate "payments" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). It is further intended that payments hereunder satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulation Section 1.409A-1(b)(4) (as a "short-term deferral"). To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder comply with Section 409A. Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under this Agreement is determined to be subject to Section 409A, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year shall not affect the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses), in no event shall any expenses be reimbursed after the last day of the calendar year following the calendar year in which Executive incurred such expenses, and in no event shall any right to reimbursement or the provision of any in-kind benefit be subject to liquidation or exchange for another benefit. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Section 409A or any damages for failing to comply with Section 409A.

16. 280G Excise Tax. Notwithstanding any other provisions in this Agreement, in the event that any payment or benefit received or to be received by Executive under this Agreement or under any other agreement between Executive and the Company or otherwise (collectively, the "**Total Payments**") would be subject (in whole or part), to any excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "**Code**"), or any successor provision thereto (the "**Excise Tax**"), then the Company will reduce the Total Payments to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax (but in no event to less than zero); provided, however, that the Total Payments will only be reduced to the extent that the after-tax value of amount received by Executive after application of the above reduction would exceed the after-tax value of amount received by Executive without application of such reduction. For this purpose, the after-tax value of an amount shall be determined taking into account all federal, state, municipal and local income, taxes, employment taxes and any Excise Tax applicable to such amount and taking into account, if applicable, the phase out of itemized deductions and personal exemptions attributable to such amount. In the case of a reduction in the Total Payments, the Total Payments will be reduced in the following order (unless reduction in another order is required to avoid adverse consequences under Section 409A of the Code, in which case, reduction will be in such other order): (i) payments that are payable in cash that are valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a) will be reduced (if necessary, to zero), with amounts that are payable last reduced first; (ii) payments and benefits due in respect of any equity valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a), with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; (iii) payments that are payable in cash that are valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with amounts that are payable last reduced first, will next be reduced; (iv) payments and benefits due in respect of any equity valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; and (v) all other non-cash benefits not otherwise described in clauses (ii) or (iv) will be next reduced pro-rata. Any reductions made pursuant to each of clauses (i)-(v) above will be made in the following manner: first, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity not subject to Section 409A of the Code, and second, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity subject to Section 409A of the Code as deferred compensation.

17. Miscellaneous Provisions.

(a) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(b) Entire Agreement. This Agreement supersedes all prior agreements and understandings between the parties, oral or written with respect to the subject matter of this Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(c) Choice of Law. The parties agree that the laws of the State of Delaware shall govern this Agreement. The federal and state courts situated in Delaware U.S.A. shall have jurisdiction and venue for any and all disputes arising out of or relating to this Agreement. If either party incurs attorney, court, mediation, arbitration, or any other litigation fees or litigation/travel expenses to enforce any rights arising out of or relating to this Agreement, the prevailing party shall be entitled to recover all of such reasonable fees and expenses from the non-prevailing party.

(d) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(e) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(f) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(g) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

(h) Survival. Sections 10 through 17 (inclusive) of this Agreement shall survive the termination of Executive's employment with the Company.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

GREENWICH LIFESCIENCES, INC.

By: _____
Name: David McWilliams
Title: Chairman of the Board

EXECUTIVE:

_____
SNEHAL PATEL

EXHIBIT A

RELEASE

Exhibit 10.8

Registration Rights Agreement

This Registration Rights (this "***Agreement***") is made and entered into as of July 23, 2010 (the "***Effective Date***") by and among Norwell, Inc., a Delaware corporation (the "***Company***") and the holders of Series A Preferred Stock (the "***Series A Preferred Stock***") as set forth on Exhibit A hereto (the "***Holders***" or the "***Investors***").

RECITALS

A. The Company and the Investors are parties to a Note Purchase Agreement dated February 7, 2010, as amended, pursuant to which Notes convertible into Series A Preferred Stock were issued (the "***Purchase Agreement***").

B. The Notes converted into Series A Preferred Stock on the Effective Date and pursuant to the Purchase Agreement, this Agreement is required to be executed by the Company and the Holders.

C. The Company expects to issue up to two million shares of Series B Preferred Stock which will become subject to this Agreement when issued.

Therefore, the parties agree as follows:

1. **Definitions.**

1.1 "***Affiliate***" means, with respect to any specified individual or entity, any other individual or entity who or that, directly or indirectly, controls, is controlled by, or is under common control with such specified individual or entity, including without limitation any partner, officer, director, manager or employee of such entity and any venture capital fund now or hereafter existing that is controlled by or under common control with one or more general partners or managing members of, or shares the same management company with, such individual or entity.

1.2 "***Common Stock***" means the Common Stock of the Company.

1.3 "***Equity Securities***" means (i) Common Stock, rights, options or warrants to purchase Common Stock, (ii) any security other than Common Stock having voting rights in the election of the Board of Directors, other than rights contingent upon a failure to pay dividends, or (iii) any security convertible into or exchangeable for any of the foregoing.

1.4 "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

1.5 "***Form S-3***" means such form under the Securities Act as is in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC (as defined below) which permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC (as defined below).

1.6 "***Holder***" means any Investor that holds Registrable Securities or securities convertible into Registrable Securities or any assignee of record of such Registrable Securities to whom rights under Section 2 have been duly assigned in accordance with Section 2.10 hereof.

1.7 "***Preferred Stock***" means the Series A Preferred Stock and the Series B Preferred Stock.

1.8 "***Register***," "***registered***" and "***registration***" refer to a registration effected by the preparation and filing of a registration statement in compliance with the Securities Act, and the declaration or ordering of effectiveness of such registration statement.

1.9 "***Registrable Securities***" means: (i) any and all shares of common stock of the Company (the "***Common Stock***") issued or issuable upon conversion of the shares of Preferred Stock, and (ii) any shares of Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right or other security which is issued as) a dividend or other distribution with respect to, in exchange for, or in replacement of, such shares of Common Stock described in clause (i); *provided, however*, that particular shares of any of the foregoing shall cease to be Registrable Securities once they have been sold to in any public offering or transferred by the Holder in a transaction in which its rights under this Agreement are not assigned in accordance with the provisions of this Agreement.

1.10 "***Registrable Securities then outstanding***" means the number of shares of Common Stock which are Registrable Securities and (i) are then issued and outstanding or (ii) are then issuable pursuant to the exercise or conversion of options, warrants or convertible securities.

1.11 "***SEC***" means the United States Securities and Exchange Commission.

1.12 "***Securities Act***" means the Securities Act of 1933, as amended.

2. **Registration Rights.**

2.1 **Demand Registration.**

(a) **Request by Holders.** If the Company shall receive at any time within six (6) months after the effective date of the first registration statement for a public offering of securities of the Company (other than a registration statement relating to the sale of securities to employees of the Company pursuant to a stock option, stock purchase or similar plan or an SEC Rule 145 transaction) a written request from the Holders of at least a majority of the Registrable Securities then outstanding, amounting to at least 500,000 shares of Registrable Securities, ("***Initiating Holders***") that the Company file a registration statement under the Securities Act covering the registration of such Registrable Securities, then the Company shall, within ten (10) business days of the receipt of such written request, give written notice of such request ("***Demand Notice***") to all Holders and, as soon as practicable, file a registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of this Section 2.

(b) **Underwriting.** If the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, then they shall so advise the Company as a part of their request made pursuant to Section 2.1(a) and the Company shall include such information in the Demand Notice. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting (unless otherwise mutually agreed by a majority in interest of the Initiating Holders and such Holder) to the extent provided herein. The underwriters will be selected by the Company and shall be reasonably acceptable to the Company. All Holders proposing to distribute their Registrable Securities through such underwriting shall enter into an underwriting agreement in customary form with the managing underwriter or underwriters selected for such underwriting. Notwithstanding any other provision of this Section 2.1, if the managing underwriters advise the Company in writing that marketing factors require a limitation of the number of securities to be underwritten, then the Company shall so advise all Holders of Registrable Securities that would otherwise be registered and underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be reduced as required by the underwriters and allocated among the Holders on a pro rata basis according to the number of Registrable Securities held by each Holder requesting registration (including the Initiating Holders); *provided, however*, that the number of shares of Registrable Securities to be included in such underwriting and registration shall not be reduced unless all other securities of the Company are first entirely excluded from the underwriting and registration. Any Registrable Securities excluded and withdrawn from such underwriting shall be withdrawn from the registration.

(c) **Exceptions to Registration Obligations.** The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to this Section 2.1: (i) during the period starting with the date sixty (60) days prior to the Company's good faith estimate of the date of filing of, and ending on the date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, *provided* that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two (2) such registration; or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Section 2.3. A registration shall not be counted as "effected" for purposes of this Section 2.1 until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration and forfeit their right to one demand registration pursuant to Section 2.5.

(d) **Deferral of Registration.** Notwithstanding the foregoing, if the Company shall furnish to Holders requesting registration pursuant to this Section 2.1 a certificate signed by the President or Chief Executive Officer of the Company stating that, in the good faith judgment of the Board of Directors of the Company, it would be materially detrimental to the Company and its shareholders for such registration statement to be filed and it is therefore essential to defer the filing of such registration statement, then the Company shall have the right to defer such filing for a period of not more than 120 days following receipt of the request of the Initiating Holders; *provided, however*, that the Company may not utilize this right more than once in any 12-month period.

(e) **Other Company Shares.** If the managing underwriters have not limited the Registrable Securities to be underwritten, the Company may include securities for its own account or for the account of others in such registration if the managing underwriters so agree and if the number of Registrable Securities which would otherwise have been included in such registration and underwriting will not thereby be limited.

2.2 **Company Registration.**

(a) **Notice to Holders.** If (but without any obligation to do so) the Company proposes to register (including for this purpose a registration effected by the Company for shareholders other than the Holders) any of its stock in connection with the public offering of such stock (other than a registration relating solely to the issuance of securities by the Company pursuant to a stock option, stock purchase or similar benefit plan or a SEC Rule 145 transaction, or a registration in which the only stock being registered is stock issuable upon conversion of debt securities that are also being registered), the Company shall promptly give each Holder written notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Section 2.2(c), use all reasonable efforts to cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration.

(b) **Right to Terminate Registration.** The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses of such withdrawn registration shall be borne by the Company in accordance with Section 2.5.

(c) **Underwriting.** If a registration of which the Company gives notice under this Section 2.2 is for an underwritten offering, then the Company shall so advise the Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their Registrable Securities through such underwriting shall enter into an underwriting agreement in customary form with the managing underwriters selected for such underwriting. Notwithstanding any other provision of this Agreement, if the managing underwriters advise the Company in writing that marketing factors require a limitation of the number of securities to be underwritten, then the managing underwriters may exclude shares (including Registrable Securities) from the registration and the underwriting, and the number of shares that may be included in the registration and the underwriting shall be allocated, first, to the Company, and second, to each of the Holders requesting inclusion of their Registrable Securities in such registration statement on a pro rata basis based on the total number of Registrable Securities then held by each such Holder; *provided, however*, that no such reduction shall reduce the amount of securities of the selling Holders included in the registration below 20% of the total amount of securities included in such registration, unless such offering is the initial public offering, in which event all Registrable Securities may be excluded. In no event will shares of any other selling shareholder be included in such registration which would reduce the number of shares that may be included by selling Holders without the written consent of not less than a majority in interest of the selling Holders. If any Holder disapproves of the terms of any such underwriting, such Holder may elect to withdraw therefrom by written notice to the Company and the managing underwriters. Any Registrable Securities excluded or withdrawn from such underwriting shall be excluded and withdrawn from the registration. For any Holder that is a partnership, limited liability company or corporation, the partners or members, retired partners or members or shareholders of such Holder, the estates and immediate family members of any of the foregoing persons and any trusts for the benefit of any of the foregoing persons shall be deemed to be a single Holder, and any pro rata reduction with respect to such Holder shall be based upon the aggregate amount of shares carrying registration rights owned by all entities and individuals included in such Holder.

2.3 **Form S-3 Registration.** Following its initial public offering, the Company shall use commercially reasonable efforts to qualify for registration on Form S-3 or its successor form or forms. In case the Company shall receive from any Holder or Holders of at least 20% of the Registrable Securities then outstanding a written request or requests that the Company effect a registration on Form S-3 or a successor form and any related qualification or compliance with respect to all or a part of the Registrable Securities owned by such Holder or Holders, then the Company shall:

(a) promptly give written notice of the proposed registration and the Holder's or Holders' request therefor, and any related qualification or compliance, to all other Holders of Registrable Securities; and

(b) as soon as practicable, use commercially reasonable efforts to effect such registration as would permit or facilitate the sale and distribution of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such request, together with all or such portion of the Registrable Securities of any other Holders joining in such request as are specified in a request given to the Company within fifteen (15) days after the S-3 Notice is given; *provided, however*, that the Company shall not be obligated to effect any such registration pursuant to this Section 2.3:

(i) if Form S-3 is not then available for such offering by the Holders;

(ii) if the Holders, together with the holders of any other securities of the Company entitled to and requesting inclusion in such registration, propose to sell Registrable Securities and such other securities (if any) at an aggregate price to the public of less than $1,000,000;

(iii) if the Company furnishes to the Holders a certificate signed by the President or Chief Executive Officer of the Company stating that, in the good-faith judgment of the Board of Directors of the Company, it would be materially detrimental to the Company and its shareholders for such registration to be effected at such time, in which event the Company shall have the right to defer the filing of the Form S-3 registration statement for a period of not more than 120 days after receipt of the request of the Initiating Holders under this Section 2.3; *provided, however*, that the Company shall not invoke this right more than once in any twelve (12) month period; or

(iv) if the Company has, within the twelve (12) month period preceding the date of such request, already effected one registration on Form S-3 for the Holders pursuant to this Section 2.3**.**

(c) Registrations effected pursuant to this Section 2.3 shall not be counted as demands for registration effected pursuant to Section 2.1.

(d) If the registration is for an underwritten offering, the provisions of Section 2.1(b) hereof shall apply to such registration.

2.4 **Obligations of the Company.** Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use commercially reasonable efforts to cause such registration statement to become effective, and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for up to one hundred twenty (120) days.

(b) prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such number of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of the Registrable Securities owned by them that are included in such registration;

(d) use commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue sky laws of such states or other jurisdictions as shall be reasonably requested by the selling Holders, *provided* that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriters of such offering (it being understood and agreed that, as a condition to the Company's obligations under this clause (e), each Holder participating in such underwriting shall also enter into and perform its obligations under such an agreement);

(f) notify each Holder of Registrable Securities covered by such registration statement at any time when a prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(g) in the event of an underwritten public offering, use its best efforts to furnish, at the request of the managing underwriters, on the date that such Registrable Securities are delivered to the underwriters for sale, (i) an opinion, dated as of such date, of the counsel representing the Company for the purposes of such registration, in form and substance customarily given to underwriters in an underwritten public offering, addressed to the underwriters, and (ii) a "comfort" letter dated as of such date, from the independent public accountants of the Company, in form and substance customarily given by independent public accountants to underwriters in an underwritten public offering, addressed to the underwriters;

(h) use commercially reasonable efforts to cause all such Registrable Securities registered pursuant hereunder to be listed on each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(i) provide a transfer agent and registrar for all Registrable Securities registered pursuant to such registration statement and a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration; and

(j) promptly make available for inspection by the selling Holders, any managing underwriter participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents and properties of the Company and cause the Company's officers, directors, employees and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant or agent in connection with any such registration statement. This inspection right is necessary to enable the selling Holders and underwriters to undertake their due-diligence investigation in connection with the distribution. In facilitating the due-diligence investigations, the Company must be sensitive to its obligations under Regulation FD.

(k) **Furnish Information.** It shall be a condition precedent to the obligations of the Company to take any action pursuant to Sections 2.1, 2.2 or 2.3 hereof that the selling Holders shall furnish to the Company such information regarding themselves, the Registrable Securities held by them and the intended method of disposition of such securities as shall be required to timely effect the registration of their Registrable Securities.

2.5 **Expenses.** All expenses (other than underwriting discounts and commissions and stock transfer taxes and fees) incurred in connection with a registration pursuant to Sections 2.1, 2.2 and 2.3 including, without limitation, registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of counsel for the Company shall be borne by the Company. Notwithstanding the foregoing, the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Sections 2.1 or 2.3 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all participating Holders shall bear such expenses on a pro rata basis based on the number of Registrable Securities that were to requested be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities then outstanding agree to forfeit their right to one demand registration pursuant to Section 2.1.

2.6 **Delay of Registration.** No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any such registration as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.7 **Indemnification.** In the event any Registrable Securities are included in a registration statement under Sections 2.1, 2.2 or 2.3 hereof:

(a) **By the Company.** To the extent permitted by law, the Company shall indemnify and hold harmless each Holder, the partners, members, officers and directors of each Holder, legal counsel and accountants for each Holder, any underwriter (as defined in the Securities Act) for such Holder and each person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any expenses, losses, claims, damages or liabilities (joint or several) to which they may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such expenses, losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each a ***"Violation"***):

(i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto;

(ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or

(iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any federal or state securities law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any federal or state securities law in connection with the offering covered by such registration statement;

and the Company shall reimburse each such Holder, partner, officer or director, underwriter or controlling person for any legal or other expenses reasonably incurred by them, as incurred, in connection with investigating or defending any such loss, claim, damage liability or action; *provided, however*, that the indemnity agreement contained in this Section 2.7(a) shall not apply to amounts paid in settlement of any such expense, loss, claim, damage, liability or action if such settlement is effected without the consent of the Company (which consent shall not be unreasonably withheld), nor shall the Company be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, partner, officer or director, underwriter or controlling person expressly for use in connection with such registration by such Holder, partner, officer, director, underwriter or controlling person.

(b) **By Selling Holders.** To the extent permitted by law, each selling Holder shall indemnify and hold harmless the Company, each of its directors, each of its officers who have signed the registration statement, each person, if any, who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter and any other Holder selling securities under such registration statement or any of such other Holder's partners, directors or officers or any person who controls such Holder within the meaning of the Securities Act or the Exchange Act, against any expenses, losses, claims, damages or liabilities (joint or several) to which any of the foregoing persons may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such expenses, losses, claims, damages or liabilities (or actions in respect thereto) arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation arises out of or is based on actions or omissions made in reliance upon and in conformity with written information furnished by such Holder expressly for use in connection with such registration; and each such Holder shall reimburse the Company and such other persons for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; *provided, however*, that the indemnity agreement contained in this Section 2.7(b) shall not apply to amounts paid in settlement of any such expense, loss, claim, damage, liability or action if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and *provided further*, that the total amounts payable in indemnity by a Holder under this Section 2.7(b) in respect of any Violation shall not exceed the net proceeds received by such Holder in the registered offering out of which such Violation arises except in the case of fraud or willful misconduct by such Holder.

(c) **Notice.** Promptly after receipt by an indemnified party under this Section 2.7 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.7, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, jointly with any other indemnifying party to which notice has been given, to assume the defense thereof with counsel mutually satisfactory to the parties; *provided, however,* that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.7, but the omission so to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.7.

(d) **Contribution.** In order to provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Section 2.7 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.7 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Section 2.7; then, and in each such case, such parties will contribute to the aggregate expenses, losses, claims, damages or liabilities to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of the indemnifying party and the indemnified party in connection with the Violation that resulted in such expense, loss, claim, damage or liability as well as other equitable considerations. The relative fault of such parties shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact or the omission or alleged omission of a material fact relates to information supplied by the indemnifying party or indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; *provided, however*, that, in any such case, (A) no such Holder will be required to contribute any amount in excess of the net proceeds from the sale of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (B) no individual or entity guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any individual or entity who was not guilty of such fraudulent misrepresentation; and *provided further*, that in no event shall a Holder's liability pursuant to this Section 2.7(d), when combined with the amounts paid or payable by such Holder pursuant to Section 2.7(b), exceed the net proceeds from the offering received by such Holder, except in the case of willful misconduct or fraud by such Holder.

(e) **Survival.** Unless otherwise superseded by an underwriting agreement entered into in connection with the offering, the obligations of the Company and Holders under this Section 2.7 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.8 **Rule 144 Reporting.** With a view to making available the benefits of certain rules and regulations of the SEC which may at any time permit the sale of the Registrable Securities to the public without registration, after such time as a public market exists for the Common Stock, the Company agrees to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times after the effective date of the first registration under the Securities Act filed by the Company for an offering of its securities to the general public;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company as to its compliance with the reporting requirements of said Rule 144 (at any time after ninety (90) days after the effective date of the first registration statement filed by the Company for an offering of its securities to the general public), and of the Securities Act and the Exchange Act (at any time after it has become subject to the reporting requirements of the Exchange Act), (ii) a copy of the most recent annual or quarterly report of the Company and (iii) such other reports and documents of the Company as a Holder may reasonably request in availing itself of any rule or regulation of the Commission allowing a Holder to sell any such securities without registration (at any time after the Company has become subject to the reporting requirements of the Exchange Act).

2.9 "**Market Stand-Off" Agreement.** Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriters, during the period commencing on the effective date of registration statement relating to any registered public offering of the Company's Common Stock and ending on the date specified by the Company and the managing underwriters (such period not to exceed one hundred eighty (180) days or, if required by such managing underwriters, such longer period of time as is necessary to enable such underwriters to issue a research report or make a public appearance that relates to an earnings release or announcement by the Company within twenty (20) days before or after the date that is one hundred eighty (180) days after the effective date of the registration statement relating to the initial public offering, but in any event not to exceed two hundred ten (210) days following the effective date of the registration statement relating to such offering) (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Section 2.9 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall be applicable to the Holders only if all officers, directors and shareholders individually owning more than one percent (1%) of the Company's outstanding Common Stock are subject to the same restrictions. The underwriters in connection with the offering are intended third-party beneficiaries of this Section 2.9 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the managing underwriters in the offering that are consistent with this Section 2.9 or that are necessary to give further effect thereto.

In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Registrable Securities of each Holder (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

2.10 **Assignment of Registration Rights.** The rights to cause the Company to register Registrable Securities pursuant to this Section 2 may be assigned to a transferee or assignee in connection with any transfer or assignment of Registrable Securities by the Holder, *provided* that (i) such transfer or assignment may otherwise be effected in accordance with applicable securities laws, (ii) written notice is promptly given to the Company and (iii) such transferee or assignee agrees to be bound by the provisions of this Agreement, *provided* that all such transferees or assignees agree in writing to appoint a single representative as their attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Section 2.

2.11 **Termination of Registration Rights.** The Company's obligations pursuant to Sections 2.1, 2.2 and 2.3 shall terminate (i) three (3) years after the closing date of the Company's first firmly underwritten public offering of its Common Stock pursuant to a Registration Statement filed with, and declared effective by, the SEC under the Securities Act or (ii) as to any Holder, at such time following such initial public offering, as all Registrable Securities that such Holder holds or has the right to acquire may immediately be sold in any three-month period without registration pursuant to Rule 144 under the Securities Act.

2.12 **Limitations on Subsequent Registration Rights.** From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that provides such holder or prospective holder with registration rights with respect to such securities unless (i) such other registration rights are subordinate to the registration rights granted to the Holders hereunder and the inclusion of such securities will not reduce the amount of the Registrable Securities of the Holders that are included in a given registration and (ii) the holders of such rights are subject to market standoff obligations no more favorable to such persons than those contained herein, provided however, that the Company may add signatories to this Agreement representing up to two (2) million shares of the Company's Series B Preferred Stock.

Miscellaneous.

2.13 **Notices.** Any notice, request or other communication required or permitted hereunder shall be in writing and shall be deemed to have been duly given (i) if delivered to Investor, by electronic mail at the email address set forth below such Investor's signature, and (ii) if to the Company, by regular mail, at 415 Jackson Hill Street, Houston, Texas 77007

Any party hereto may by notice so given, change its address for future notices hereunder.

2.14 **Successors and Assigns.** Each Investor agrees that it may not assign any of its rights or obligations hereunder unless such rights and obligations are assigned by such Investor to an individual or entity to which Registrable Securities are transferred by such Investor pursuant to Section 2.10. Such assignee shall be deemed an "Investor" for purposes of this Agreement, *provided* that such assignment shall be contingent upon the assignee providing a written instrument to the Company notifying the Company of such assignment and agreeing in writing to be bound by the terms of this Agreement. Except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and shall be binding upon, the successors and permitted assigns of the parties hereto.

2.15 **Amendments and Waivers.** Any provision of this Agreement may be amended and the observance thereof may be waived, either generally or in a particular instance and either retroactively or prospectively, only with the written consent of the Company and the holders of a majority of the Registrable Securities; *provided, however*, that this Agreement may not be amended and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor unless such amendment or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). The Company shall give prompt notice of any amendment hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment or waiver. Any amendment or waiver effected in accordance with this Section 2.15 shall be binding upon each Investor, each permitted successor or assignee of such Investor and the Company.

2.16 **Entire Agreement.** This Agreement, together with all the exhibits hereto, constitutes and contains the entire agreement and understanding of the parties with respect to the subject matter hereof and supersedes any and all prior negotiations, correspondence, agreements, understandings, duties or obligations between the parties with respect to the subject matter hereof.

2.17 **Governing Law.** This Agreement shall be governed by and construed exclusively in accordance with the laws of the State of New York.

2.18 **Severability.** If any provision of this Agreement is held to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the balance of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

2.19 **Delays or Omissions.** No delay or omission to exercise any right, power or remedy accruing to any party under Agreement upon any breach or default of any other party under this Agreement shall impair any such right, power or remedy of the nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or waiver of or acquiescence in any similar breach or default theretofore or thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default therefore or thereafter occurring. All remedies, either under this Agreement or by law or otherwise afforded to any Holder, shall be cumulative and not alternative.

2.20 **Captions.** The captions to sections of this Agreement have been inserted for identification and reference purposes only and shall not be used to construe or interpret this Agreement.

2.21 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

2.22 **Costs and Attorneys' Fees.** In the event that any action, suit or other proceeding is instituted concerning or arising out of this Agreement or any transaction contemplated hereunder, the prevailing party shall recover all of such party's costs and attorneys' fees incurred in each such action, suit or other proceeding, including any and all appeals or petitions therefrom.

2.23 **Adjustments for Recapitalization Events.** Wherever in this Agreement there is a reference to a specific number of shares of Common Stock or Preferred Stock of the Company or a specific dollar amount per share, then, upon the occurrence of any stock split, stock dividend, reverse stock split or similar recapitalization event affecting such shares, the specific number of shares or dollar amount so referenced in this Agreement, if any, shall automatically be proportionally adjusted to reflect the effect on the outstanding shares of such class or series of stock of such recapitalization event.

2.24 **Aggregation of Stock.** All shares held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement.

2.25 **Additional Investors.** Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of the Preferred Stock after the date hereof pursuant to the Purchase Agreement, any purchaser of such shares of Preferred Stock may become a party to this Agreement by executing and delivering a counterpart signature page to this Agreement, and thereafter shall be deemed an "Investor" and "Holder" for all purposes hereunder, without the need for any consent, approval or signature of any Investor.

[Remainder of This Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date and year first above written.

Company:

Norwell, Inc.

By: _____
Snehal Petal, Chief Financial Officer
and Secretary

Investors

_____
Snehal S. Patel Roth IRA
snehalpatel2@yahoo.com

_____
Snehal S. Patel
snehalpatel2@yahoo.com

_____
Dave McWilliams
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_____
Eric Rothe
ericrothe@msn.com

_____
Chris Lentz
chris.lentz@comcast.net

_____
Joel Vanderhoof
jv@cambriacapital.com

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Amendment No. 1 to Form S-1 of our report dated April 2, 2020, except for Note 8, which is dated June 22, 2020, with respect to the audited financial statements of Greenwich LifeSciences, Inc. for the years ended December 31, 2019 and 2018. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the references to us under the heading "Experts" in such Registration Statement.

/s/ MaloneBailey, LLP
www.malonebailey.com
Houston, Texas
June 22, 2020