

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

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:

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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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
			Emerging growth company <input checked="" type="checkbox"/>

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	\$ 13,500,000	\$ 1,752.30
Total:	\$ 23,500,000	\$ 3,050.30

- (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.

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 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 4,500,000 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.

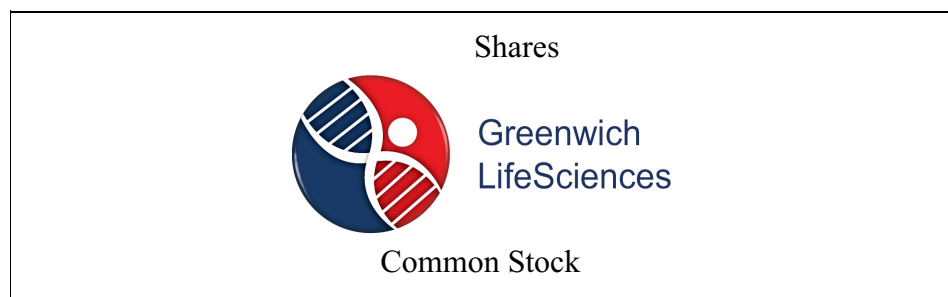
We have included in this Registration Statement, after the financial statements, a set of alternate pages to reflect the foregoing differences of the Selling Stockholder Prospectus as compared to the Prospectus.

The sales of our securities registered in the Prospectus and the shares of our common stock registered in the Selling Stockholder Prospectus may result in two offerings taking place concurrently, which could affect the price and liquidity of, and demand for, our securities. 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 May 29, 2020

PROSPECTUS



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

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

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⁾	\$ _____	\$ _____

- (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 99 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters a 45-day option to purchase up to _____ 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

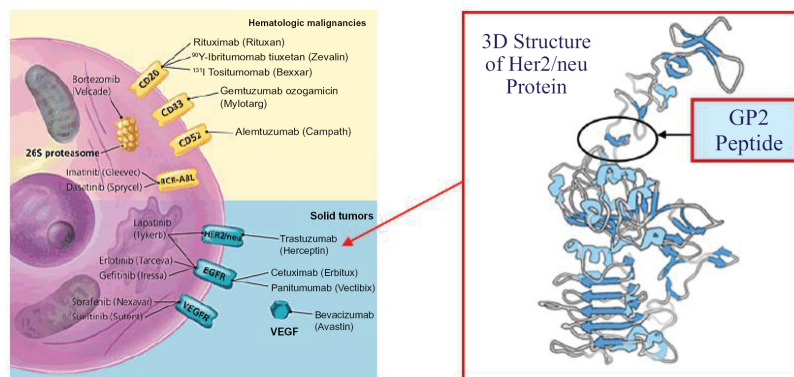
The Henry M. Jackson Foundation, or HJF, out-licenses technology of the United States military and it conducts research and manages clinical trials. We entered into an exclusive license agreement with HJF pursuant to which we have been granted an exclusive worldwide license to GP2. The GP2 issued patents 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.

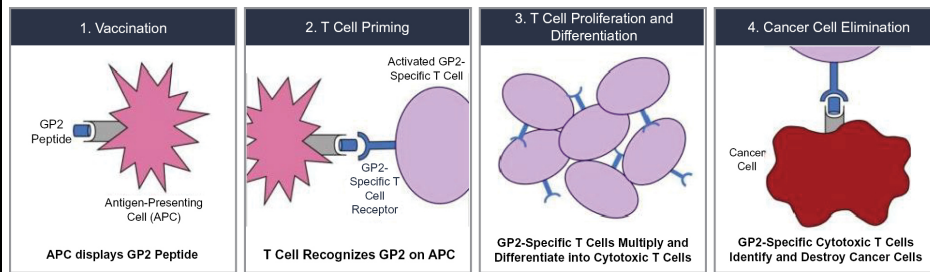
Our Product Candidate

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	Shares
Common stock to be outstanding immediately after this offering	shares (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 shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$, or approximately \$ if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of \$ 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 upon the closing of this offering to Aegis Capital Corp., as representative of the underwriters, warrants that will be exercisable during a four-year period commencing one year from the effective date of this 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	Our executive officers, directors, and certain of our stockholders, 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 22,928,014 shares of our common stock outstanding as of May 15, 2020, and excludes as of that date:

- 4,060,896 shares of common stock issuable upon conversion of 4,060,896 shares 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 \$ per share, the midpoint of the range set forth on the cover page of this prospectus. The “Original Series A Price” means \$0.10 per share, subject to adjustment. The “Series A Conversion Price” means \$0.10 per share, subject to adjustment;
- 345,132 shares of common stock issuable upon conversion of 345,132 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 \$ per share, the midpoint of the range set

forth on the cover page of this prospectus. The “Original Series B Price” means \$0.50 per share, subject to adjustment. The “Series B Conversion Price” means \$0.50 per share, subject to adjustment;

- 177,750 shares of common stock issuable upon conversion of 177,750 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 \$ per share, the midpoint of the range set forth on the cover page of this prospectus. The “Original Series C Price” means \$1.00 per share, subject to adjustment. The “Series C Conversion Price” means \$1.00 per share, subject to adjustment;
- 703,762 shares of common stock issuable upon conversion of 703,762 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 \$ per share, the midpoint of the range set forth on the cover page of this prospectus. The “Original Series D Price” means \$2.00 per share, subject to adjustment. The “Series D Conversion Price” means \$2.00 per share, subject to adjustment;
- 1,872,800 shares of common stock subject to future vesting issued to members of management and directors;
- 4,000,000 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan.
- 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 \$ (assuming an initial public offering price of \$ 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:

- a -for-1 stock split of our common stock effected on , 2020 pursuant to which (i) every 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- 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 paid in cash;
- the conversion of all of outstanding Series A Preferred Stock into an aggregate of 4,060,896 shares of our common stock, the conversion of all of outstanding Series B Preferred Stock into an aggregate of 345,132 shares of our common stock, the conversion of all of outstanding Series C Preferred Stock into an aggregate of 177,750 shares of our common stock and the conversion of all of outstanding Series D Preferred Stock into an aggregate of 703,762 shares of our common stock upon the closing of this offering; and
- no exercise by the underwriters of their option to purchase an additional 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⁾	\$ (0.57)	\$ (3.12)	\$ (0.01)	\$ (0.27)
Weighted average common shares outstanding – basic and diluted ⁽¹⁾	6,028,778	541,991	22,686,427	541,991

(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	\$ 7
Working capital deficit	(1,440)	(1,440)	
Total assets	26	26	
Total liabilities	1,447	1,447	
Accumulated deficit	(27,458)	(27,574)	
Total stockholders’ deficit	(1,421)	(1,421)	

- (1) On a pro forma basis to reflect the issuance of an aggregate of 138,050 shares of common stock in April and May 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 \$ 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 5,287,540 shares of common stock upon closing of the offering.

- (3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ 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 \$, 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 1,000,000 million 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 \$.

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 \$27.5 million 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 December 31, 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 selfpay 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's pending 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 Invents 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 inseparable 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 May 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 4,500,000 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 declining 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 % 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 \$ per share, representing the difference between the assumed initial public offering price of \$ 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 \$(0.06). 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 will 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 May 15, 2020, we have designated 4,200,000 shares of preferred stock as Series A Preferred Stock, of which 4,060,896 are issued and outstanding; 390,000 shares of preferred stock as Series B Preferred Stock, of which 345,132 are issued and outstanding; 205,000 shares of preferred stock as Series C Preferred Stock, of which 177,750 are issued and outstanding; and 2,000,000 shares of preferred stock as Series D Preferred Stock, of which 703,762 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 \$ million, based on an assumed initial public offering price of \$ 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 \$ 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 \$ per share would increase or decrease the net proceeds from this offering by approximately \$ 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 March 31, 2020:

- on an actual basis;
- on a pro forma basis to reflect the issuance of an aggregate of 138,050 shares of common stock in April and May 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 _____ 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 \$ _____ 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 5,287,540 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	\$
Short term notes payable to related parties	635	635	
Stockholders' deficit:			
Preferred stock, par value \$0.001 per share; 6,795,000 shares authorized, 5,287,540 issued and outstanding, actual; shares authorized, issued and outstanding, pro forma; shares authorized, issued and outstanding, pro forma as adjusted	5	5	
Common stock, par value \$0.001 per share; 100,000,000 shares authorized, 22,789,664 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	23	23	
Additional paid-in capital	26,009	26,125	
Accumulated deficit	(27,458)	(27,574)	
Total stockholders' deficit	(1,421)	(1,421)	
Total capitalization	\$ (1,421)	\$ (1,421)	\$

- (1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ 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 \$ _____ 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 1,000,000 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 \$ _____ 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 22,789,964 shares of our common stock outstanding as of March 31, 2020, assumes no exercise by the underwriters of their over-allotment option and excludes:

- 2,010,850 shares of common stock subject to future vesting issued to members of management and directors;
- 4,000,000 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan; and
- _____ 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 \$ _____ (assuming an initial public offering price of \$ _____ 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 \$(0.06) per share of common stock, based on 22,789,964 shares of common stock outstanding at March 31, 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 138,050 shares of common stock in April and May 2020 in consideration for services rendered, our pro forma net tangible book value (deficit) as of March 31, 2020 was \$(1,440,051), or \$(0.06) per share of common stock.

After giving further effect to (i) the sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ 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 5,287,540 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 \$ _____ million, or \$ _____ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ _____ per share to existing stockholders and immediate dilution of \$ _____ 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	\$ _____
Pro forma net tangible book value per share as of March 31, 2020	\$ (0.06)
Increase in pro forma as adjusted net tangible book value per share attributable to new investors in this offering	_____
Pro forma as adjusted net tangible book value per share immediately after this offering	_____
Dilution per share to new investors in this offering	\$ _____

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ 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 \$ _____ per share and the dilution to new investors purchasing common stock in this offering by \$ _____ 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 1,000,000 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 \$ _____ per share and decrease the dilution to new investors purchasing common stock in this offering by \$ _____ 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 1,000,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value after this offering by \$ _____ per share and increase the dilution to new investors purchasing common stock in this offering by \$ _____ 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 \$ _____ per share. This represents an increase in pro forma as adjusted net tangible book value of \$ _____ per share to existing stockholders and dilution in pro forma as adjusted net tangible book value of \$ _____ per share to new investors.

The number of shares of our common stock to be outstanding after this offering is based on 22,789,964 shares of our common stock outstanding as of March 31, 2020, assumes no exercise by the underwriters of their over-allotment option and excludes:

- 2,010,850 shares of common stock subject to future vesting issued to members of management and directors;
- 4,000,000 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan; and
- 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 \$ (assuming an initial public offering price of \$ 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 \$ 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		%	\$	%	\$
New investors					\$
Total		%	\$	%	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ 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 \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 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 1,000,000 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 \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 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 % 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 % 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⁾	\$ (0.57)	\$ (3.12)	\$ (0.01)	\$ (0.27)
Weighted average common shares outstanding – basic and diluted ⁽¹⁾	6,028,778	541,991	22,686,427	541,991

(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,
	2019	2018	2020 (unaudited)
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)	(27,458)
Total stockholders' deficit	(1,350)	(10,120)	(1,421)
Total liabilities and stockholders' deficit	27	109	26

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 March 31, 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 December 31, 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 December 31, 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 December 31, 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 March 31, 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 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.

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.

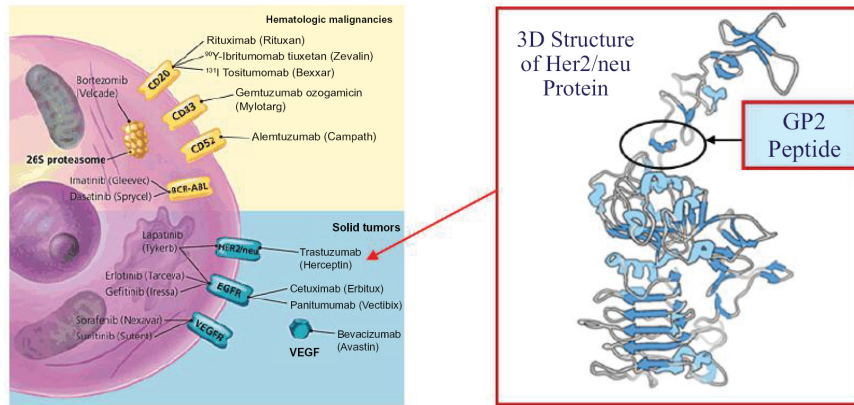
Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b)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

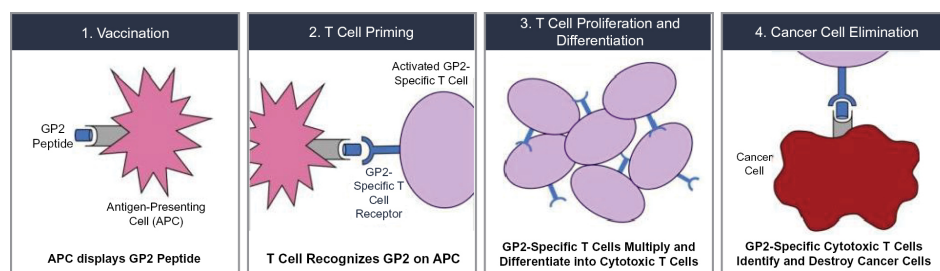
Cancer immunotherapies seek to stimulate an individual's own immune system to selectively attack cancer cells while not affecting normal cells or delivering certain immune system components in order to inhibit the spread of cancer. Cancer immunotherapy drugs are a new method of cancer treatment which 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.

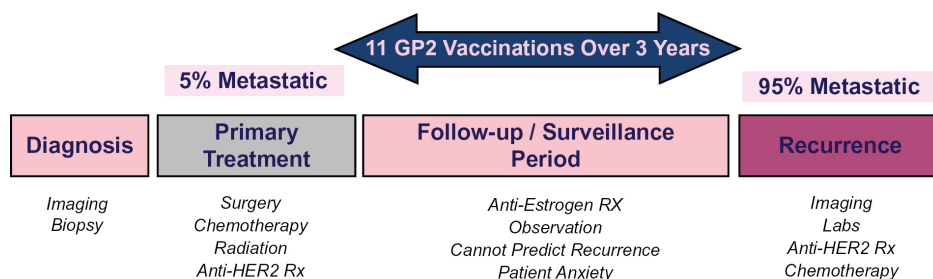


Breast Cancer Treatment Approach — Adjuvant & Neoadjuvant Treatments

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 deescalation 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 <ul style="list-style-type: none"> Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-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 <ul style="list-style-type: none"> Phase I Safety Trial of the GP2 + GM-CSF Vaccine in Combination with the Helper Peptide AE37 + GM-CSF Vaccine 14 patients treated with GP2 + AE37 + GM-CSF 	Trial Completed
GP2 Phase I Clinical Trial — Combination with Trastuzumab <ul style="list-style-type: none"> Phase Ib Trial of Combination Immunotherapy with HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients 17 patients treated with GP2 + GM-CSF + trastuzumab 	Trial Completed
First GP2 Phase I Clinical Trial <ul style="list-style-type: none"> Phase Ib Trial of HER2/<i>neu</i> Peptide (GP2) Vaccine in Breast Cancer Patients 18 patients treated with GP2 + GM-CSF 	Trial Completed

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 + GMCSF. 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 + GMCSF 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 + GMCSF 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.

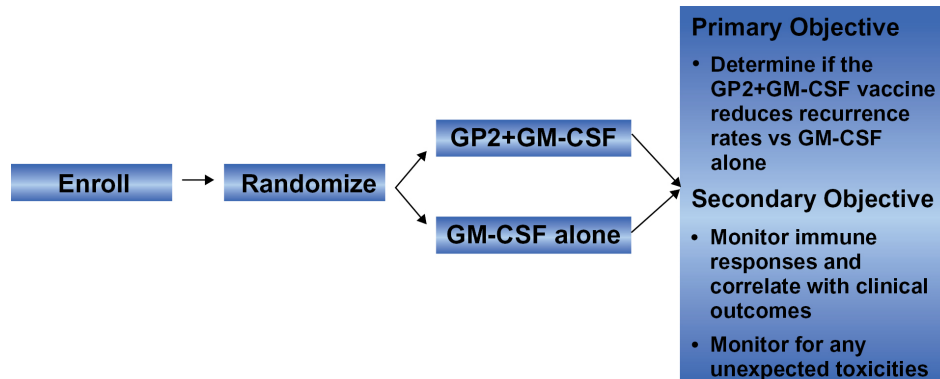
Phase II Clinical Trial

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 diseasefree and immunocompetent after having completed standard of care therapy.
- The primary endpoint was to determine if GP2 + GMCSF 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.



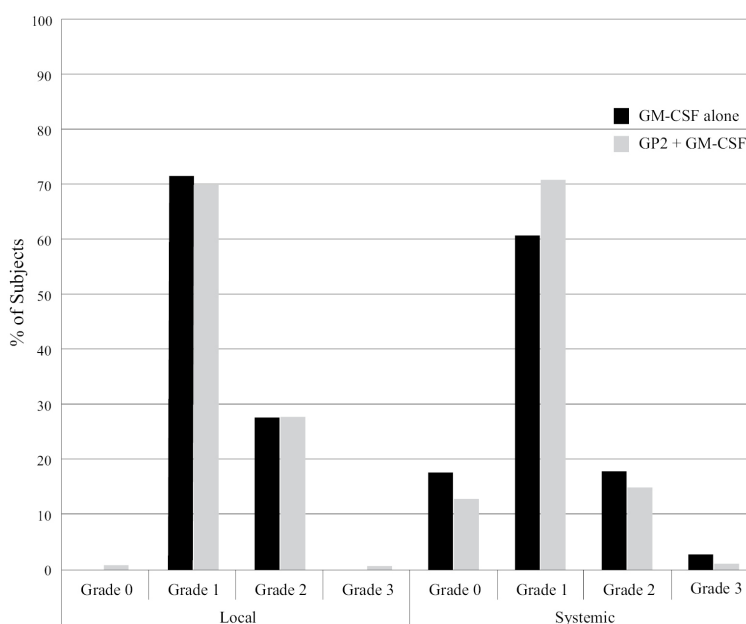
The Phase IIb clinical trial closed in December 2018. The median 5 year followup data from this Phase IIb clinical trial is currently being collected and analyzed. The median 5 year data, other than the top-line data described in the table below, has yet to be published.

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.

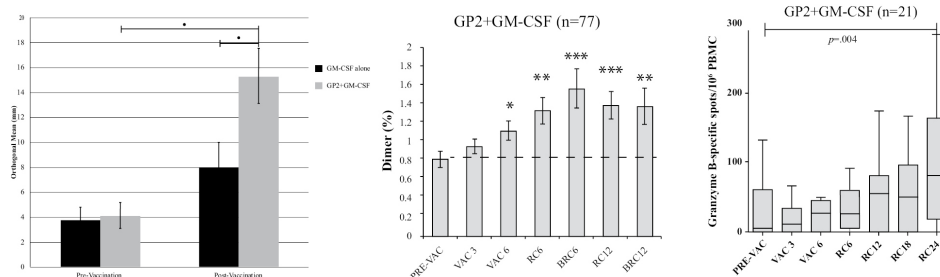
In both patient populations, GP2 was shown to be well tolerated, consisting of primarily injection site reactions which are caused by GM-CSF and can be mitigated by reducing the GM-CSF dose (and then the GP2 dose, if necessary). No SAEs were reported in the GP2 treated patients. Maximum local and systemic 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.

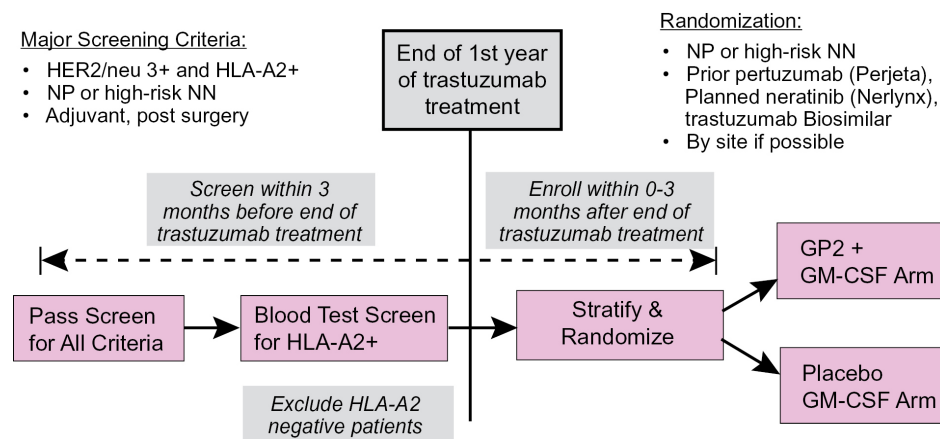
- Immune response was observed peaking after 6 months compared to baseline, measured by Delayed Type Hypersensitivity (“DTH”) skin test using GP2) and immunological assay. DTH response rate for treated patients is very high. Orthogonal mean baseline versus six months: 4.1 ± 1.1 mm versus 15.3 ± 2.2 mm (\pm 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 multibillion 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/ <i>neu</i> 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	

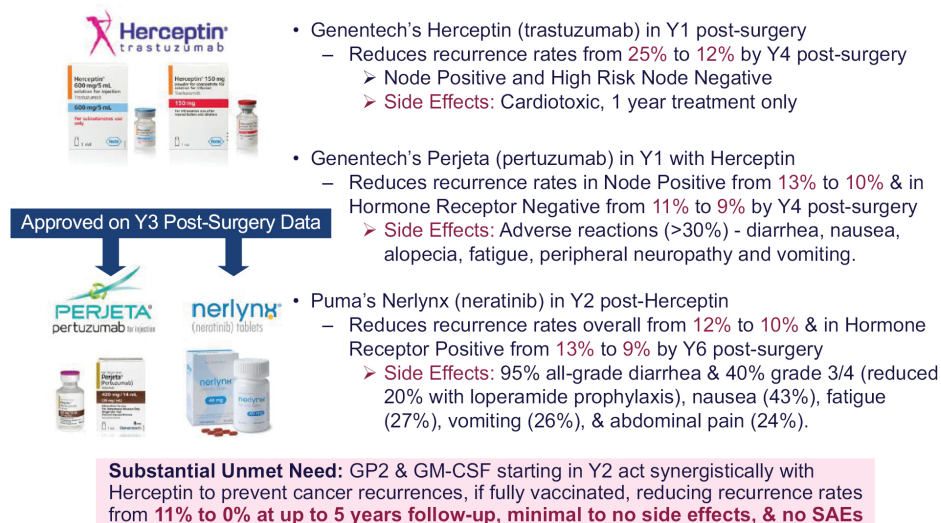
Competition

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 Squibb 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 Kadcyra (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 (atezolizumab). 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 Kadcyra and Enhertu.



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 540,991 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 May 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 May 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.

MANAGEMENT

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 May 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 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 Sales 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 395,833 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) 12,000,000 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through September 30, 2019 and (ii) 4,423,128 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	1,604,167 ⁽¹⁾	1,347,500

- (1) We granted Mr. Patel 2,000,000 shares of common stock on September 30, 2019 for compensation and incentives of which 250,000 vested immediately upon grant, and the balance, or 1,750,000 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 75,000 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, 6,249 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 50,000 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, 4,164 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 50,000 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, 4,164 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) 400,000 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 711,375 shares of our common stock in exchange for warrants to purchase shares of common stock. Mr. Rothe received (i) 100,000 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 680,856 shares of our common stock in exchange for warrants to purchase shares of common stock. Mr. Hallock received (i) 1,375,000 shares of our common stock in exchange for related party payables for the periods from January 1, 2010 through June 30, 2016 and (ii) 562,500 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.

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 4,000,000 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 4,000,000 (the “ISO Limit”). The number of shares available for issuance under the 2019 Plan constitutes 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 4,000,000 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 4,000,000.
- 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 4,000,000 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 4,000,000 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 May 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 May 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 May 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 January 1, 2010 totaled \$12 million. As of September 30, 2019, our officers and directors owned outstanding warrants to acquire 6,849,909 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 21,099,909 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. We expect to 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 May 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 May 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 28,215,554 shares of common stock issued and outstanding as of May 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	19,076,454 ⁽¹⁾	67.38%	
F. Joseph Daugherty	98,610 ⁽²⁾	*	
David McWilliams	1,587,700 ⁽³⁾	5.63 %	
Eric Rothe	794,842 ⁽⁴⁾	2.82 %	
Kenneth Hallock	762.630 ⁽⁵⁾	2.70 %	
All current named executive officers and directors as a group (5 persons)	22,320,236	78.78%	

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

(1) Consists of (i) 736,835 shares of common stock owned by Snehal Patel, (ii) 472,050 shares of common stock owned by Snehal Patel IRA, (iii) 6,423,128 shares of common stock owned by Patel Family Trust 1, (iv) 3,525,000 shares of common stock owned by Patel Family Trust 2, (v) 3,550,000 shares of common stock owned by Patel Family Trust 3, (vi) 471,116 shares of common stock underlying shares of Series A Preferred Stock owned by Snehal Patel, (vii) 3,055,890 shares of common stock underlying shares of Series A Preferred Stock owned by Snehal Patel IRA, (viii) 36,673 shares of common stock underlying shares of Series B Preferred Stock owned by Snehal Patel, (ix) 205,000 shares of common stock underlying shares of Series B Preferred Stock owned by Kinnary Patel IRA, (x) 8,000 shares of common stock underlying shares of Series B Preferred Stock owned by Snehal Patel IRA, (xi) 27,750 shares of common stock underlying shares of Series C Preferred Stock owned by Snehal Patel, (xii) 90,000 shares of common stock underlying shares of Series C Preferred Stock owned by Snehal Patel IRA, (xiii) 238,987 shares of common stock underlying shares of Series D Preferred Stock owned by Snehal Patel, (xiv) 121,025 shares of common stock underlying shares of Series D Preferred Stock owned by Kinnary Patel IRA and (xv) 115,000 shares of common stock underlying shares of Series D Preferred Stock owned by Snehal Patel IRA. Excludes 1,263,890 shares of common stock held by Snehal Patel which vest in 26 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 126,390 shares of common stock which vest in 26 equal monthly installments.

- (3) Consists of (i) 1,132,289 shares of common stock, (ii) 407,452 shares of common stock underlying shares of Series A Preferred Stock, (iii) 20,459 shares of common stock underlying shares of Series B Preferred Stock, (iv) 10,000 shares of common stock underlying shares of Series C Preferred Stock and (v) 17,500 shares of common stock underlying shares of Series D Preferred Stock. Excludes 54,170 shares of common stock which vest in 26 equal installments.
- (4) Excludes 36,120 shares of common stock which vest in 26 equal monthly installments.
- (5) Consists of (i) 451,380 shares of common stock owned by the Kenneth and Annette Hallock Revocable Trust (the "Hallock Trust"), (ii) 50,000 shares of common stock underlying shares of Series B Preferred Stock owned by the Hallock Trust, (iii) 50,000 shares of common stock underlying shares of Series C Preferred Stock owned by the Hallock Trust and (iv) 211,250 shares of common stock underlying shares of Series D Preferred Stock owned by the Hallock Trust. Excludes 36,120 shares of common stock which vest in 26 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.

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 May 15, 2020, there were 25 record holders of our securities. As of May 15, 2020 there were 22,928,014 shares of common stock issued and outstanding. In addition, as of May 15, 2020, 4,060,896 shares of Series A Preferred Stock, 345,132 shares of Series B Preferred Stock, 177,750 shares of Series C Preferred Stock and 703,762 shares of Series D Preferred Stock were issued and outstanding which shares of preferred stock are convertible into an aggregate of 5,287,540 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 May 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.”

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 \$ (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, executive officers, and holders owning 5% or more of our outstanding stock 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 four-year period commencing one year from the effective date of this 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 this four year period, the exercising holder will receive a 3% cash fee. 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 December 31, 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.
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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

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	<u>\$ 26,671</u>	<u>\$ 108,545</u>
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	<u>1,377,089</u>	<u>10,228,599</u>
Stockholders' deficit		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,582,889 and 541,991 shares issued and outstanding as of December 31, 2019 and 2018, respectively	22,583	542
Preferred stock, \$0.001 par value; 6,795,000 shares authorized; Series A preferred stock: 4,060,896 issued and outstanding as of December 31, 2019 and 2018	4,061	4,061
Series B preferred stock: 345,132 issued and outstanding as of December 31, 2019 and 2018	345	345
Series C preferred stock: 177,750 issued and outstanding as of December 31, 2019 and 2018	178	178
Series D preferred stock: 703,762 and 653,762 issued and outstanding as of December 31, 2019 and 2018, respectively	704	704
Additional paid-in capital	25,835,702	13,662,800
Accumulated deficit	(27,213,991)	(23,788,684)
Total stockholders' deficit	<u>(1,350,418)</u>	<u>(10,120,054)</u>
Total liabilities and stockholders' deficit	<u>\$ 26,671</u>	<u>\$ 108,545</u>

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	<u>\$ (3,425,307)</u>	<u>\$ (1,689,655)</u>
Per share information:		
Net loss per common share, basic and diluted	\$ (0.57)	\$ (3.12)
Weighted average common shares outstanding, basic and diluted	6,028,778	541,991

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	541,991	\$ 542	5,237,540	\$ 5,238	\$ 13,562,850	\$ (22,099,029)	\$ (8,530,399)
Preferred Stock Sold	—	—	50,000	50	99,950	—	100,000
Net loss						(1,689,655)	(1,689,655)
Balances, December 31, 2018	541,991	542	5,287,540	5,288	13,662,800	(23,788,684)	(10,120,054)
Exchange of related party payables and warrants for common stock	21,393,823	21,394	—	—	11,978,606	—	12,000,000
Stock-based compensation	647,075	647	—	—	194,296	—	194,943
Net loss						(3,425,307)	(3,425,307)
Balances, December 31, 2019	<u>22,582,889</u>	<u>\$ 22,583</u>	<u>5,287,540</u>	<u>\$ 5,288</u>	<u>\$ 25,835,702</u>	<u>\$ (27,213,991)</u>	<u>\$ (1,350,418)</u>

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 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	<u>(293,267)</u>	<u>(114,952)</u>
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	<u>215,000</u>	<u>200,000</u>
Net increase (decrease) in cash	<u>(78,267)</u>	<u>85,048</u>
Cash, beginning of period	85,102	54
Cash, end of period	<u>\$ 6,835</u>	<u>\$ 85,102</u>
Non-cash investing and financing activities:		
Common stock to settle related party payable	12,000,000	

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
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.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

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 4,060,896 shares of the Company's common stock issuable upon conversion of the Company's Series A Preferred Stock, 345,132 shares of the Company's common stock issuable upon conversion of the Company's Series B Preferred Stock, 177,750 shares of the Company's common stock issuable upon conversion of the Company's Series C Preferred Stock, and 703,762 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 7,143,823 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.

GREENWICH LIFESCIENCES, INC.
NOTES TO 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.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

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 7,143,823 warrants were cancelled on September 30, 2019, as all related party payables and all warrants were exchanged for an aggregate of 21,393,823 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 December 31, 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 540,991 shares of the Company's common stock valued at \$0.10 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.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

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 22,040,898 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 4 million 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 7,143,823 warrants were exchanged for 21,393,823 shares of the Company's common stock, and 415,000 shares of the Company's common stock were issued upfront at no value in consideration for services and 2,425,000 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, 207,075 shares of the 2,425,000 shares of the common stock grant has vested at \$173,943 value and 2,217,925 shares remain unvested and unrecognized at \$1,863,057 value.

On December 30, 2019, the Company issued a consultant 25,000 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 7,143,823 warrants to \$0 on the modification date of September 30, 2019, and thus the Company exchanged the 7,143,823 warrants for 7,143,823 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 50,000 shares of Series D Preferred Stock from a custodian in 2018 at the original issuance price of \$2.00 per share.

As of December 31, 2019, the Company has 4,060,896 shares of Series A Preferred Stock issued and outstanding with a purchase price and conversion price of \$0.10 per share.

GREENWICH LIFESCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS

7. Stockholders' Deficit (cont.)

As of December 31, 2019, the Company has 345,132 shares of Series B Preferred Stock issued and outstanding with a purchase price and conversion price of \$0.50 per share with anti-dilution protection of 50% of the subsequent round price if a subsequent round is priced at or below \$1.00 per share and a floor of \$0.20 per share to limit the anti-dilution protection.

As of December 31, 2019, the Company has 177,750 shares of Series C Preferred Stock issued and outstanding with a purchase price and conversion price of \$1.00 per share with anti-dilution protection of 66.7% of the subsequent round price if a subsequent round is priced at or below \$1.50 per share and a floor of \$0.30 per share to limit the anti-dilution protection.

As of December 31, 2019, the Company has 703,762 shares of Series D Preferred Stock issued and outstanding with a purchase price and conversion price of \$2.00 per share with anti-dilution protection of 80% of the subsequent round price if a subsequent round is priced at or below \$2.50 per share and a floor of \$0.30 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
807,020	\$ 0.10	July 27, 2020
415,000	\$ 0.50	September 20, 2020
424,750	\$ 1.00	September 30, 2020
1,582,503	\$ 2.00	June 30, 2021
1,614,550	\$ 2.00	June 30, 2022
700,000	\$ 2.00	June 30, 2023
750,000	\$ 2.00	June 30, 2024
850,000	\$ 2.00	June 30, 2025
7,143,823		

The weighted average exercise price of outstanding warrants to purchase common stock at December 31, 2018 was \$1.64 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
7,143,823	(7,143,823)	—

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	<u>\$ 25,770</u>	<u>\$ 26,671</u>
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	<u>1,446,886</u>	<u>1,377,089</u>
Total liabilities	<u>1,446,886</u>	<u>1,377,089</u>
Stockholders' deficit		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,789,964 and 22,582,889 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	22,790	22,583
Preferred stock, \$0.001 par value; 6,795,000 shares authorized; Series A preferred stock: 4,060,896 issued and outstanding as of March 31, 2020 and December 31, 2019	4,061	4,061
Series B preferred stock: 345,132 issued and outstanding as of March 31, 2020 and December 31, 2019	345	345
Series C preferred stock: 177,750 issued and outstanding as of March 31, 2020 and December 31, 2019	178	178
Series D preferred stock: 703,762 issued and outstanding as of March 31, 2020 and December 31, 2019	704	704
Additional paid-in capital	26,009,438	25,835,702
Accumulated deficit	<u>(27,458,632)</u>	<u>(27,213,991)</u>
Total stockholders' deficit	<u>(1,421,116)</u>	<u>(1,350,418)</u>
Total liabilities and stockholders' deficit	<u>\$ 25,770</u>	<u>\$ 26,671</u>

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	<u>\$ (244,641)</u>	<u>\$ (148,731)</u>
Per share information:		
Net loss per common share, basic and diluted	\$ (0.01)	\$ (0.27)
Weighted average common shares outstanding, basic and diluted	22,686,427	541,991

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	541,991	\$ 542	5,287,540	\$ 5,288	\$ 13,662,800	\$ (23,788,684)	\$ (10,120,054)
Net loss						(148,731)	(148,731)
Balances, March 31, 2019	<u>541,991</u>	<u>\$ 542</u>	<u>5,287,540</u>	<u>\$ 5,288</u>	<u>\$ 13,662,800</u>	<u>\$ (23,937,415)</u>	<u>\$ (10,268,785)</u>
Balances, December 31, 2019	22,582,889	\$ 22,583	5,287,540	\$ 5,288	\$ 25,835,702	\$ (27,213,991)	\$ (1,350,418)
Stock-based compensation	207,075	207	—	—	173,736	—	173,943
Net loss						(244,641)	(244,641)
Balances, March 31, 2020	<u>22,789,964</u>	<u>\$ 22,790</u>	<u>5,287,540</u>	<u>\$ 5,288</u>	<u>\$ 26,009,438</u>	<u>\$ (27,458,632)</u>	<u>\$ (1,421,116)</u>

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.

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

1. Organization and Description of the Business

Greenwich LifeSciences, Inc. (the “Company”) was incorporated in the state of Delaware in 2006 under the name Norwell, Inc. In March 2018, Norwell, Inc. changed its name to Greenwich LifeSciences, Inc. The Company is developing a breast cancer immunotherapy focused on preventing the recurrence of breast cancer following surgery.

2. 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 7,143,823 shares of the Company’s common stock.

As of March 31, 2020 and 2019, the Company has common stock equivalents related to 4,060,896 shares of the Company’s common stock issuable upon conversion of the Company’s Series A Preferred Stock, 345,132 shares of the Company’s common stock issuable upon conversion of the Company’s Series B Preferred Stock, 177,750 shares of the Company’s common stock issuable upon conversion of the Company’s Series C Preferred Stock, and 703,762 shares of the Company’s common stock issuable upon conversion of the Company’s Series D Preferred Stock.

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

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	22,686,427	541,991
Net loss per common share, basic and diluted	\$ (0.01)	\$ (0.27)

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.

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

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 4 million 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 7,143,823 warrants were exchanged for 21,393,823 shares of the Company's common stock, and 415,000 shares of the Company's common stock were issued upfront at no value in consideration for services and 2,425,000 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, 414,150 of the 2,425,000 shares of the common stock grant had vested at \$347,886 value and 2,010,850 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 \$0.10 to \$2.00 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.

Shares



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	\$ 3,050.30
FINRA filing fee	\$ *
The Nasdaq Capital Market initial listing fee	\$ *
Blue sky qualification fees and expenses	\$ *
Transfer agent and registrar fees	\$ *
Accounting fees and expenses	\$ *
Legal fees and expenses	\$ *
Printing and engraving expenses	\$ *
Miscellaneous	\$ *
Total	\$ *

* To be filed by amendment.

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 7,143,823 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 21,393,823 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 415,000 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 207,075 shares of the Company's common stock for services rendered.

On December 30, 2019, the Company issued a consultant 25,000 shares of the Company's common stock for services rendered.

From January 1, 2020 to May 1, 2020, the Company issued officers, directors and a consultant 345,125 shares 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*	<u>Amended and Restated Certificate of Incorporation, currently in effect</u>
3.2*	<u>Amendment to Amended and Restated Certificate of Incorporation dated March 2, 2018</u>
3.3*	<u>Amendment to Amended and Restated Certificate of Incorporation dated September 9, 2019</u>
3.4**	Form of Second Amended and Restated Certificate of Incorporation, to be effective immediately prior to the closing of this offering
3.5*	<u>Amended and Restated Bylaws, currently in effect</u>
3.6**	Form of Second Amended and Restated Bylaws, to be effective immediately prior to the closing of this offering
4.1**	Specimen Stock Certificate evidencing the shares of common stock
5.1**	Opinion of Sheppard, Mullin, Richter & Hampton LLP
10.1+*	<u>2019 Equity Incentive Plan</u>
10.2+*	<u>Form of Indemnification Agreement with directors and executive officers</u>
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
23.1*	<u>Consent of MaloneBailey, LLP, independent registered public accounting firm</u>
23.2**	Consent of Sheppard, Mullin, Richter & Hampton, LLP (included in Exhibit 5.1)
24.1	<u>Power of Attorney (included on the signature page to this registration statement)</u>

* Filed herewith.

** To be filed by amendment.

+ 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 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 29th day of May, 2020.

GREENWICH LIFESCIENCES, INC.

By: /s/ Snehal Patel

Snehal Patel

Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Snehal Patel, his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, as amended, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

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	Chief Executive Officer and Director	May 29, 2020
Snehal Patel	<i>(Principal Executive Officer and Principal Accounting and Financial Officer)</i>	
/s/ F. Joseph Daugherty	Chief Medical Officer and Director	May 29, 2020
F. Joseph Daugherty		
/s/ David McWilliams	Director	May 29, 2020
David McWilliams		
/s/ Eric Rothe	Director	May 29, 2020
Eric Rothe		
/s/ Kenneth Hallock	Director	May 29, 2020
Kenneth Hallock		

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 May 29, 2020

PROSPECTUS



Greenwich
LifeSciences

4,500,000 Shares of Common Stock

The selling stockholders plan to sell an aggregate of up to 4,500,000 shares of common stock.

The selling stockholders must sell their shares at a fixed price per share of \$, 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 or quoted on the OTCBB, OTCQX or OTCQB marketplaces. 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 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 a public offering of shares of our common stock through the underwriters (excluding 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 underwritten 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 4,500,000 shares of our common stock (the "Resale Shares").

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 28,215,554 shares of common stock issued and outstanding as of May 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⁾	500,000	1.77%	500,000	0	0%
Yosajo MI Trust 2 ⁽³⁾	500,000	1.77%	500,000	0	0%
Yosajo MI Trust 3 ⁽³⁾	500,000	1.77%	500,000	0	0%
Yosajo MA Trust 1 ⁽³⁾	500,000	1.77%	500,000	0	0%
Yosajo MA Trust 2 ⁽³⁾	500,000	1.77%	500,000	0	0%
Yosajo MA Trust 3 ⁽³⁾	500,000	1.77%	500,000	0	0%
Brent Thomas Henderson 2010 Trust ⁽⁴⁾	500,000	1.77%	500,000	0	0%
David Brian Henderson 2010 Trust ⁽⁴⁾	500,000	1.77%	500,000	0	0%
Thatcher Duncan Hallock 2010 Trust ⁽⁴⁾	500,000	1.77%	500,000	0	0%
TOTAL	4,500,000				

- (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 \$ 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 \$ 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

Delaware

PAGE 1

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 RESTATED CERTIFICATE OF "NORWELL, INC.", FILED IN THIS OFFICE ON THE NINETEENTH DAY OF APRIL, A.D. 2011, AT 2:32 O'CLOCK P.M.


A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

4211497 8100

110428748

You may verify this certificate online
at corp.delaware.gov/authver.shtml




Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 8706510

DATE: 04-20-11

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF NORWELL, INC.**

April 19, 2011

Norwell, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware ("DGCL"), does hereby certify as follows:

The present name of the corporation is Norwell, Inc. The corporation was incorporated under the name "Norwell, Inc." by the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware on August 29, 2006. This Amended and Restated Certificate of Incorporation, which restates and integrates and also further amends the provisions of the corporation's Certificate of Incorporation, was recommended to the stockholders for approval as being advisable and in the best interest of the Corporation by written action of the Board of Directors on April 19, 2011. In lieu of a meeting and vote of the stockholders, consents in writing have been signed by holders of outstanding stock having not less than the minimum number of votes that is necessary to consent to this amendment and statement, and if required, prompt notice of such action shall be given in accordance with the provisions of Section 228 of the DGCL. This Amended and Restated Certificate of Incorporation has been duly adopted by the Corporation's Board of Directors and stockholders in accordance with the applicable provisions of Sections 242 and 245 of the Delaware General Corporation Law. The Certificate of Incorporation of the Corporation is hereby amended, integrated and restated to read in its entirety as follows:

ARTICLE I

The name of this Corporation is Norwell, Inc.

ARTICLE II

Its registered office in the State of Delaware is located at 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808, County of New Castle. The name of its registered agent at such address is The Company Corporation.

ARTICLE III

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"). The Corporation shall possess and may exercise all powers and privileges necessary or convenient to affect such purpose and all powers and privileges now or hereafter conferred by the laws of the State of Delaware upon corporations formed under the DGCL.

ARTICLE IV

The total number of shares of all classes of capital stock which the Corporation shall have the authority to issue is fourteen million seven hundred ninety five thousand (14,795,000) shares which shall be divided into the following classes:

(a) Nine million five hundred thousand (9,500,000) shares of Common Stock with a par value of \$.001 per share ("Common Stock"). One thousand shares are currently issued as no par Common Stock and will be reclassified as \$.001 par value shares, with the par value allocated from the original purchase price.

(b) Four Million Two Hundred Thousand (4,200,000) shares of Series A Preferred Stock with a par value of \$.001 per share ("Series A"); and

(c) Three Hundred Ninety Thousand (390,000) shares of Series B Preferred Stock with a par value of \$.001 per share ("Series B").

(d) Two Hundred Five Thousand (205,000) shares of Series C Preferred Stock with a par value of \$.001 per share ("Series C").

(e) Five Hundred Thousand (500,000) shares of Series D Preferred Stock with a par value of \$.001 per share ("Series D").

ARTICLE V

Common Stock Dividends. Subject to any rights of holders of Series A, Series B, Series C, and Series D, the Board of Directors may declare and pay dividends on Common Stock (payable in cash, stock or other property) from time to time from any lawfully available funds, property or shares and in such amount and subject to such conditions as may be determined by the Board of Directors.

Common Stock Voting Rights. Subject to any rights of holders of Series A, Series B, Series C, and Series D to vote on a matter as a class or series, each outstanding share of Common Stock shall be entitled to one vote on each matter submitted to a vote of holders of Common Stock at a meeting of stockholders. The holders of the shares of Common Stock shall at all times, except as otherwise provided in this Certificate of Incorporation or as required by law, vote together with the holders of Series A, Series B, Series C, and Series D, as one class. Cumulative voting for the election of directors of the Corporation shall not be permitted.

Rights of Common Stock upon Liquidation, Dissolution or Winding Up. In the event of any liquidation, dissolution or winding up of the Corporation, after payment (or making provision for payment) of the debts and liabilities of the Corporation and payment of the full preferential amounts to which the holders of Series A, Series B, Series C, and Series D are entitled, the holders of Common Stock shall be entitled to receive the net balance of any remaining assets of the Corporation.

Preferred Stock. The rights, preferences, powers, privileges and restrictions, qualifications and limitations granted to and imposed on Series A, Series B, Series C, and Series D are as set forth below in this Article V.

I. Dividends. The holders of the then outstanding Series A, Series B, Series C, and Series D shall be entitled to receive, when, if and as declared by the Board of Directors, out of assets legally available therefore, on a pari passu basis with the Common Stock, dividends when, as and if declared by the Board. The right to dividends on shares of Series A, Series B, Series C,

and Series D shall not be cumulative, and no right shall accrue to holders of Series A, Series B, Series C, and Series D by reason of the fact that dividends on said shares are not declared in any period, nor shall any undeclared or unpaid dividend bear or accrue interest.

2. Liquidation Preference. In the event of a Liquidation Event (as defined below), the assets and funds of the Corporation available for distribution to stockholders shall be distributed as follows:

(a) First, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to receive, out of the assets of the Corporation legally available for distribution to its stockholders, before any payment or distribution of such assets shall be made in respect of the Corporation's Common Stock, an amount equal to \$0.10 per share of Series A Preferred Stock (the "Original Series A Price"), as adjusted for any stock splits, reverse stock splits, stock dividends and similar recapitalization events (each a "Recapitalization Event") plus all declared and unpaid dividends on such shares to the date fixed for such distribution. If, upon the occurrence of such event, the assets of the Corporation legally available for distribution are insufficient to permit the payment to the holders of Series A Preferred Stock of the full preferential amounts described in this Section 2(a), then the entire assets available for distribution to stockholders shall be distributed to the holders of the Series A Preferred Stock ratably in proportion to the full preferential amounts which they would be entitled to receive pursuant to the preceding sentence of this Section 2(a).

(b) Second, after the full preferential amount due the Series A pursuant to Section 2(a) has been paid or set aside, the holders of shares of Series B Preferred Stock then outstanding shall be entitled to receive, out of the remaining assets of the Corporation legally available for distribution to its stockholders, before any payment or distribution of such assets shall be made in respect of the Corporation's Common Stock, an amount equal to \$0.50 per share of Series B Preferred Stock (the "Original Series B Price"), as adjusted for any Recapitalization Event, plus all declared and unpaid dividends on such shares to the date fixed for such distribution. If, upon the occurrence of such event, the assets of the Corporation legally available for distribution are insufficient to permit the payment to the holders of Series B of the full preferential amounts described in this Section 2(b), then the entire assets available for distribution to stockholders shall be distributed to the holders of the Series B ratably in proportion to the full preferential amounts which they would be entitled to receive pursuant to the preceding sentence of this Section 2(b).

(c) Third, after the full preferential amount due the Series A and Series B pursuant to Section 2(a) and Section 2(b) has been paid or set aside, the holders of shares of Series C Preferred Stock then outstanding shall be entitled to receive, out of the remaining assets of the Corporation legally available for distribution to its stockholders, before any payment or distribution of such assets shall be made in respect of the Corporation's Common Stock, an amount equal to \$1.00 per share of Series C Preferred Stock (the "Original Series C Price"), as adjusted for any Recapitalization Event, plus all declared and unpaid dividends on such shares to the date fixed for such distribution. If, upon the occurrence of such event, the assets of the Corporation legally available for distribution are insufficient to permit the payment to the holders of Series C of the full preferential amounts described in this Section 2(c), then the entire assets available for distribution to stockholders shall be distributed to the holders of the Series C ratably

in proportion to the full preferential amounts which they would be entitled to receive pursuant to the preceding sentence of this Section 2(c).

(d) Fourth, after the full preferential amount due the Series A, Series B, and Series C pursuant to Section 2(a), Section 2(b) and Section 2(c) has been paid or set aside, the holders of shares of Series D Preferred Stock then outstanding shall be entitled to receive, out of the remaining assets of the Corporation legally available for distribution to its stockholders, before any payment or distribution of such assets shall be made in respect of the Corporation's Common Stock, an amount equal to \$2.00 per share of Series D Preferred Stock (the "Original Series D Price"), as adjusted for any Recapitalization Event, plus all declared and unpaid dividends on such shares to the date fixed for such distribution. If, upon the occurrence of such event, the assets of the Corporation legally available for distribution are insufficient to permit the payment to the holders of Series D of the full preferential amounts described in this Section 2(d), then the entire assets available for distribution to stockholders shall be distributed to the holders of the Series D ratably in proportion to the full preferential amounts which they would be entitled to receive pursuant to the preceding sentence of this Section 2(d).

(e) After the full preferential amounts due the holders of Series A, Series B, Series C, and Series D pursuant to Sections 2(a) and 2(b) have been paid or set aside, the remaining assets of the Corporation legally available for distribution to its stockholders, if any, shall be distributed to the holders of Common Stock ratably in proportion to the number of shares of Common Stock then held by each holder.

(f) Each of the following events shall be deemed to be a "Liquidation Event" as that term is used in this Certificate: (i) the liquidation, dissolution or winding up of the Corporation, either voluntary or involuntary, (ii) a merger, consolidation or reorganization of the Corporation into or with another entity after which the stockholders of the Corporation immediately prior to such transaction do not own, immediately following the consummation of the transaction by virtue of their shares in the Corporation or securities received in exchange for such shares in connection with the transaction, a majority of the voting power of the surviving entity in proportions substantially similar to those that existed immediately prior to such transaction, and (iii) the sale, transfer or other disposition (but not including a transfer or disposition by pledge or mortgage to a bona fide lender) of all or substantially all of the assets of the Corporation (other than to a wholly-owned subsidiary). Notwithstanding the foregoing, neither (A) a merger effected exclusively for the purpose of changing the domicile of the Corporation nor (B) the sale of shares of capital stock of the Corporation in a transaction or series of related transactions effected primarily for equity financing purposes shall be deemed a Liquidation Event.

(g) In the event of any Liquidation Event involving the distribution of assets other than cash to the stockholders of the Corporation, the value of the assets to be distributed shall be determined as follows:

(i) In the case of securities that are not subject to investment legends or other similar restrictions on free tradability,

(A) if traded on a national securities exchange or through the Nasdaq Global Market, the value shall be deemed to be the average of the closing prices of the securities over the 10 day period ending three days prior to the closing of the Liquidation Event;

(B) if actively traded over-the-counter, the value shall be deemed to be the average of (i) the average of the last bid and ask prices or (ii) the closing sale prices (whichever is applicable) over the 30 day period ending three days prior to the closing of the Liquidation Event; and

(C) if there is no active public market, the value shall be the fair market value thereof, as mutually determined by the Corporation and the holders of at least a majority of the voting power of all then outstanding shares of Series A, Series B, Series C, and Series D.

(ii) In the case of securities subject to investment restrictions or other restrictions on free marketability (other than restrictions arising solely by virtue of a stockholder's status as an affiliate or former affiliate), the value shall be based on an appropriate discount from the market value determined as above in Section 2(e) (i) to reflect the approximate fair market value thereof, as determined by the Board of Directors in the good faith exercise of its reasonable judgment.

(iii) In the case of any other property, the value shall be equal to the property's fair market value, as determined by the Board of Directors in the good faith exercise of its reasonable judgment.

3. Conversion. The holders of Series A, Series B, Series C, and Series D shall have conversion rights as follows:

(a) Right to Convert. Each share of Series A, Series B, Series C, and Series D shall be convertible, at the option of the holder thereof, at any time after the date of issuance of such share, at the office of the Corporation or any transfer agent for the Series A, Series B, Series C, and Series D, into Common Stock. The number of shares of fully paid and nonassessable Common Stock into which each share of Series A may be converted shall equal the Original Series A Price divided by the Series A Conversion Price (as defined below) in effect at the time of conversion (the "Series A Conversion Rate"). The Conversion Price for the Series A shall initially be \$0.10, and shall be subject to adjustment as provided in Section 3(d) below. The number of shares of fully paid and nonassessable Common Stock into which each share of Series B may be converted shall equal the Original Series B Price divided by the Series B Conversion Price (as defined below) in effect at the time of conversion (the "Series B Conversion Rate"). The Conversion Price for the Series B shall initially be \$0.50, and shall be subject to adjustment as provided in Section 3(d) below. The number of shares of fully paid and nonassessable Common Stock into which each share of Series C may be converted shall equal the Original Series C Price divided by the Series C Conversion Price (as defined below) in effect at the time of conversion (the "Series C Conversion Rate"). The Conversion Price for the Series C shall initially be \$1.00, and shall be subject to adjustment as provided in Section 3(d) below. The number of shares of fully paid and nonassessable Common Stock into which each share of Series D may be converted shall equal the Original Series D Price divided by the Series D

Conversion Price (as defined below) in effect at the time of conversion (the “Series D Conversion Rate”). The Conversion Price for the Series D shall initially be \$2.00, and shall be subject to adjustment as provided in Section 3(d) below.

(b) Automatic Conversion. Each share of Series A shall automatically be converted into fully paid and nonassessable shares of Common Stock, at the then effective Series A 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 Series A, (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 Corporation with an entity whose shares of common stock trade publicly, such that its shares of common stock are held by the public and are available for purchase by investors in listed exchanges or over the counter markets. Each share of Series B shall automatically be converted into fully paid and nonassessable shares of Common Stock, at the then effective Series B 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 Series B, (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 Corporation with an entity whose shares of common stock trade publicly, such that its shares of common stock are held by the public and are available for purchase by investors in listed exchanges or over the counter markets. Each share of Series C shall automatically be converted into fully paid and nonassessable shares of Common Stock, at the then effective Series C 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 Series C, (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 Corporation with an entity whose shares of common stock trade publicly, such that its shares of common stock are held by the public and are available for purchase by investors in listed exchanges or over the counter markets. Each share of Series D shall automatically be converted into fully paid and nonassessable shares of Common Stock, at the then effective Series D 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 Series D, (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 Corporation with an entity whose shares of common stock trade publicly, such that its shares of common stock are held by the public and are available for purchase by investors in listed exchanges or over the counter markets.

(c) Mechanics of Conversion. Before any holder of Series A, Series B, Series C, or Series D shall be entitled to convert the same into shares of Common Stock, such holder shall surrender the certificate or certificates therefore (or a reasonably acceptable affidavit and indemnity undertaking in the case of a lost, stolen or destroyed certificate), duly endorsed, at the headquarters of the Corporation or of any transfer agent for the Corporation and shall give written notice to the Corporation at such office that the holder elects to convert the same and shall state therein the name or names in which the certificate or certificates for shares of Common Stock are to be issued (except that no such written notice of election to convert shall be necessary in the event of an Automatic Conversion as described above). The Corporation shall,

as soon as practicable thereafter, issue and deliver at such office to such holder of Series A, Series B, Series C, or Series D, or to the nominee or nominees of such holder, a certificate or certificates for the number of shares of Common Stock to which such holder shall be entitled as aforesaid. Such conversion shall be deemed to have been made immediately prior to the close of business on the date of such surrender of the shares of Series A, Series B, Series C, or Series D to be converted (except that, in the case of an Automatic Conversion, such conversion shall be deemed to have been made immediately prior to the event triggering the Automatic Conversion) and the person or persons entitled to receive the shares of Common Stock issuable upon such conversion shall be treated for all purposes as the record holder or holders of such shares of Common Stock on such date. Upon the occurrence of either of the events specified in Section 3(b) above, the outstanding shares of Series A, Series B, Series C, and Series D shall be converted automatically without any further action by the holders of such shares and whether or not the certificates representing such shares are surrendered to the Corporation or its transfer agent; *provided, however*, that the Corporation shall not be obligated to issue certificates evidencing the shares of Common Stock issuable upon such conversion unless either the certificates evidencing such shares of Series A, Series B, Series C, and Series D are delivered to the Corporation or its transfer agent as provided above, or the holder notifies the Corporation or its transfer agent that such certificates have been lost, stolen or destroyed and executes an agreement satisfactory to the Corporation to indemnify the Corporation against any loss incurred by it in connection with such certificates.

(d) Adjustments to Conversion Price for Dilutive Issuances.

(i) Special Definitions. For purposes of this Section 3(d), the following definitions shall apply:

(A) "Original Issue Date" shall mean, with respect to any shares of Series A, Series B, Series C, or Series D, the date on which shares of such series are first issued by the Corporation.

(B) "Additional Shares of Common Stock" shall mean all shares of Common Stock issued (or, pursuant to Section 3(d) (ii) below, deemed to be issued) by the Corporation after the Original Issue Date, other than:

(1) shares of Common Stock issued upon conversion of Series A, Series B, Series C, and Series D;

(2) shares of Common Stock issued or issuable to officers, directors or employees of, or consultants to, the Corporation pursuant to any stock option plan or agreement or other stock incentive program or agreement approved by the Board of Directors.

(3) shares issued or issuable to financial institutions, equipment lessors, landlords, business partners or other entities in connection with commercial credit arrangements, equipment financings, real estate transactions, joint ventures or other partnering arrangements or similar transactions approved by the Board of Directors;

(4) shares issued upon exercise or conversion of any warrants that are outstanding as of the date of this Certificate;

(5) shares issued in connection with the acquisition by the Corporation of voting control or all or substantially all of the assets of another business entity in a transaction approved by the Board of Directors;

(6) shares for which an adjustment is made pursuant to Section 3(d) (vi); or

(7) shares issued in connection with acquisitions or licenses of technology or intellectual property in transactions that are approved by the Board of Directors.

(C) “Options” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire either Common Stock or Convertible Securities (as defined below).

(D) “Convertible Securities” shall mean any evidences of indebtedness, shares of Series A, Series B, Series C, and Series D or other securities convertible into or exchangeable for Common Stock.

(ii) Deemed Issue of Additional Shares of Common Stock. In the event the Corporation at any time or from time to time after the Original Issue Date shall issue any Options or Convertible Securities or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the following provisions shall apply:

(A) The maximum number of shares (as set forth in the instrument relating thereto without regard to any provisions contained therein for a subsequent adjustment of such number) of Common Stock issuable upon the exercise of such Options or upon the conversion or exchange of such Convertible Securities shall be deemed to have been issued as of the time of the issuance of such Option or Convertible Security or, in case such a record date shall have been fixed, as of the close of business on such record date.

(B) Except as provided in paragraphs (C) and (D) below, no further adjustment in the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, and Series D Conversion Price shall be made upon the subsequent issue of Convertible Securities or shares of Common Stock upon the exercise of such Options or conversion or exchange of such Convertible Securities.

(C) If such Options or Convertible Securities by their terms provide, with the passage of time or otherwise, for any change in the consideration payable to the Corporation or the number of shares of Common Stock issuable upon the exercise, conversion or exchange thereof (other than a change resulting from the antidilution provisions of such Options or Convertible Securities), the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, and Series D Conversion Price computed upon the original issue thereof (or upon the occurrence of a record date with respect thereto) and any subsequent adjustments based thereon shall, upon any such increase or decrease becoming effective, be recomputed to reflect such increase or decrease insofar as it affects such Options or the rights of conversion or exchange under such Convertible Securities; provided, however, that such recomputed Series A Conversion Price shall not exceed the Series A Conversion Price that would have been in effect

had the original issuance of Options or Convertible Securities not been deemed to constitute an issuance of Additional Shares of Common Stock; provided, however, that such recomputed Series B Conversion Price shall not exceed the Series B Conversion Price that would have been in effect had the original issuance of Options or Convertible Securities not been deemed to constitute an issuance of Additional Shares of Common Stock; provided, however, that such recomputed Series C Conversion Price shall not exceed the Series C Conversion Price that would have been in effect had the original issuance of Options or Convertible Securities not been deemed to constitute an issuance of Additional Shares of Common Stock; and provided further, however, provided, however, that such recomputed Series D Conversion Price shall not exceed the Series D Conversion Price that would have been in effect had the original issuance of Options or Convertible Securities not been deemed to constitute an issuance of Additional Shares of Common Stock.

(D) Upon the expiration of any such Options or Convertible Securities, the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, and Series D Conversion Price to the extent in any way affected by or recomputed due to the issuance of such Options or Convertible Securities, shall be recomputed to reflect the issuance of only the number of shares of Common Stock actually issued upon the exercise of such Options or Convertible Securities.

(iii) *Adjustment of Series A Conversion Price for Dilutive Issuances.* In the event the Corporation shall issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 3(d)(ii)), in the event of a dividend or other distribution payable in additional shares of Common Stock or in the event the outstanding shares of Common Stock shall be subdivided, combined or consolidated, by stock split, reverse stock split or similar event, into a greater or lesser number of shares of Common Stock, after the Original Issue Date of Series A, without consideration or for a consideration per share less than the Series A Conversion Price Conversion Price in effect immediately prior to such issuance, then and in each such event the Series A Conversion Price shall be reduced to a price (rounded to the nearest one one-hundredth of one cent) equal to such Series A Conversion Price, multiplied by a fraction:

(x) the numerator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of shares of Common Stock which the aggregate consideration received by the Corporation for the total number of Additional Shares of Common Stock so issued would purchase at the Series A Conversion Price in effect immediately prior to such issuance; and

(y) the denominator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of Additional Shares of Common Stock so issued.

For the purposes of this Section 3(d) (iii), the number of shares of Common Stock deemed to be outstanding shall be deemed to include the Common Stock issuable upon full exercise and conversion of all then outstanding Options and Convertible Securities.

(iv) Adjustment of Series B Conversion Price for Dilutive Issuances. In the event the Corporation shall issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 3(d)(ii)), in the event of a dividend or other distribution payable in additional shares of Common Stock or in the event the outstanding shares of Common Stock shall be subdivided, combined or consolidated, by stock split, reverse stock split or similar event, into a greater or lesser number of shares of Common Stock, after the Original Issue Date of Series B, without consideration or for a consideration per share less than the Series B Conversion Price in effect immediately prior to such issuance, then and in each such event the Series B Conversion Price shall be reduced to a price (rounded to the nearest one one-hundredth of one cent) equal to such Series B Conversion Price, multiplied by a fraction:

(x) the numerator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of shares of Common Stock which the aggregate consideration received by the Corporation for the total number of Additional Shares of Common Stock so issued would purchase at the Series B Conversion Price in effect immediately prior to such issuance; and

(y) the denominator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of Additional Shares of Common Stock so issued. For the purposes of this Section 3(d) (iv), the number of shares of Common Stock deemed to be outstanding shall be deemed to include the Common Stock issuable upon full exercise and conversion of all then outstanding Options and Convertible Securities.

(v) Adjustment of Series C Conversion Price for Dilutive Issuances. In the event the Corporation shall issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 3(d)(ii)), in the event of a dividend or other distribution payable in additional shares of Common Stock or in the event the outstanding shares of Common Stock shall be subdivided, combined or consolidated, by stock split, reverse stock split or similar event, into a greater or lesser number of shares of Common Stock, after the Original Issue Date of Series C, without consideration or for a consideration per share less than the Series C Conversion Price in effect immediately prior to such issuance, then and in each such event the Series C Conversion Price shall be reduced to a price (rounded to the nearest one one-hundredth of one cent) equal to such Series C Conversion Price, multiplied by a fraction:

(x) the numerator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of shares of Common Stock which the aggregate consideration received by the Corporation for the total number of Additional Shares of Common Stock so issued would purchase at the Series C Conversion Price in effect immediately prior to such issuance; and

(y) the denominator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of Additional Shares of Common Stock so issued. For the purposes of this Section 3(d) (v), the number of shares of Common Stock deemed to be outstanding shall be deemed to

include the Common Stock issuable upon full exercise and conversion of all then outstanding Options and Convertible Securities.

(vi) Adjustment of Series D Conversion Price for Dilutive Issuances. In the event the Corporation shall issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 3(d)(ii)), in the event of a dividend or other distribution payable in additional shares of Common Stock or in the event the outstanding shares of Common Stock shall be subdivided, combined or consolidated, by stock split, reverse stock split or similar event, into a greater or lesser number of shares of Common Stock, after the Original Issue Date of Series D, without consideration or for a consideration per share less than the Series D Conversion Price in effect immediately prior to such issuance, then and in each such event the Series D Conversion Price shall be reduced to a price (rounded to the nearest one one-hundredth of one cent) equal to such Series D Conversion Price, multiplied by a fraction:

(x) the numerator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of shares of Common Stock which the aggregate consideration received by the Corporation for the total number of Additional Shares of Common Stock so issued would purchase at the Series D Conversion Price in effect immediately prior to such issuance; and

(y) the denominator of which is equal to the number of shares of Common Stock outstanding or deemed to be outstanding immediately prior to such issuance plus the number of Additional Shares of Common Stock so issued. For the purposes of this Section 3(d) (vi), the number of shares of Common Stock deemed to be outstanding shall be deemed to include the Common Stock issuable upon full exercise and conversion of all then outstanding Options and Convertible Securities.

(vii) Determination of Consideration. For purposes of this Section 3(d), the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(A) Cash and Property. Such consideration shall:

(1) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation before deducting any reasonable discounts, commissions or other expenses allowed, paid or incurred by the Corporation for any underwriting or otherwise in connection with the issuance and sale thereof;

(2) insofar as it consists of property other than cash, be computed at the fair value thereof at the time of such issue, as determined by the Board of Directors in the good faith exercise of its reasonable business judgment; and

(3) in the event Additional Shares of Common Stock are issued together with other securities or other assets of the Corporation for consideration that covers both, be the proportion of such consideration so received, computed as provided in clauses (1) and (2) above, as determined by the Board of Directors in the good faith exercise of its reasonable business judgment.

(B) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Section 3(d) relating to Options and Convertible Securities shall be equal to:

(x) the total amount, if any, received or receivable by the Corporation as consideration for the issuance of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, divided by

(y) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities.

(viii) Other Adjustments and Matters Related to Conversion.

(A) Other Distributions. In case the Corporation shall distribute to holders of its Common Stock shares of its capital stock (other than shares of Common Stock and other than as otherwise subject to adjustment pursuant to this Section 3(d)), stock or other securities of other persons, evidences of indebtedness issued by the Corporation or other persons, assets (excluding cash dividends) or options or rights (excluding options to purchase and rights to subscribe for Common Stock or other securities of the Corporation convertible into or exchangeable for Common Stock), or shall fix a record date for determination of holders of Common Stock entitled to receive such a distribution, then, in each such case, provision shall be made so that the holders of Series A, Series B, Series C, and Series D shall be entitled to receive, upon conversion thereof, in addition to the number of shares of Common Stock receivable thereupon, the distribution that they would have received had the Series A, Series B, Series C, or Series D been converted into Common Stock on the date of such event (or on the record date with respect thereto, if such record date is fixed) and had they thereafter, during the period from the date of such event to and including the date of conversion, retained such distribution receivable by them as aforesaid during such period, subject to all other adjustments called for during such period under this Section 3 with respect to the rights of the holders of Series A, Series B, Series C, and Series D.

(B) Recapitalizations and Reorganizations. In the case of any capital recapitalization or reorganization (other than a subdivision, combination or other recapitalization provided for elsewhere in this Section 3 or a Liquidation Event provided for in Section 2), or the fixing of any record date for determination of holders of Common Stock affected by such recapitalization or reorganization, provision shall be made so that the holders of Series A, Series B, Series C, and Series D shall be entitled to receive, upon conversion thereof, the type and number of shares of stock or other securities or property of the Corporation or otherwise that they would have received had their Series A, Series B, Series C, or Series D been converted into Common Stock on the date of such event (or on the record date with respect

thereto, if such record date is fixed) and had they thereafter, during the period from the date of such event to and including the date of conversion, retained such shares of stock or other securities or property receivable by them as aforesaid during such period, subject to all other adjustments called for during such period under this Section 3 with respect to the rights of the holders of Series A, Series B, Series C, and Series D. In any such case, appropriate adjustment shall be made in the application of the provisions of this Section 3 to the end that the provisions of this Section 3 shall be applicable after the recapitalization or reorganization to the greatest extent practicable.

(C) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, or Series D Conversion Price pursuant to this Section 3, the Corporation at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to each such holder of a share of Series A, Series B, Series C, or Series D a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based including the consideration received for any Additional Shares of Common Stock issued. The Corporation shall, upon the written request at any time of any holder of Series A, Series B, Series C, or Series D, furnish or cause to be furnished to such holder a like certificate setting forth (i) such adjustments and readjustments, (ii) the Series A Conversion Price at the time in effect for Series A, the Series B Conversion Price at the time in effect for Series B, the Series C Conversion Price at the time in effect for Series C, and the Series D Conversion Price at the time in effect for Series D, as applicable and (iii) the number of shares of Common Stock and the type and amount, if any, of other property which at the time would be received upon the conversion of a share of Series A, Series B, Series C, or Series D, as applicable.

(e) Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of shares of Series A, Series B, Series C, or Series D. In lieu of any fractional shares to which the holder of Series A, Series B, Series C, or Series D would otherwise be entitled, the Corporation may either pay cash equal to such fraction multiplied by the fair market value of one share of Common Stock as determined by the Board of Directors or it may round up to the nearest share. The number of whole shares issuable to each holder of Series A, Series B, Series C, or Series D upon such conversion shall be determined on the basis of the number of shares of Common Stock issuable upon conversion of the total number of shares being converted into Common Stock by such holder at that time.

(f) Notices of Record Date. In the event (i) the Corporation shall take a record of the holders of its capital stock for the purpose of entitling them to receive a dividend or other distribution (other than a cash dividend), (ii) of any capital reorganization, reclassification or recapitalization (other than a subdivision or combination of its outstanding shares of Common Stock), or (iii) of a Liquidation Event pursuant to Section 2, then, and in any such case, the Corporation shall cause to be mailed to each holder of record of the Series A, Series B, Series C, and Series D at the address of record of such stockholder as set forth on the Corporation's books, at least 20 days prior to the earliest date hereinafter specified, a notice stating the material terms of the proposed transaction and the date on which (x) a record is to be taken for the purpose of such dividend or distribution or (y) such reorganization, reclassification, recapitalization or Liquidation Event is to take place and the date, if any is to be fixed, as of which holders of

capital stock of record shall be entitled to exchange their shares of capital stock for securities or other property deliverable upon such reorganization, reclassification, recapitalization or Liquidation Event; *provided, however*, that such notice period may be shortened upon the written consent of holders of Series A, Series B, Series C, and Series D that are entitled to such notice rights or similar notice rights and that represent at least a majority of the voting power of all then outstanding shares of Series A, Series B, Series C, and Series D (voting together as a single class on a converted basis). If any material change in the facts set forth in the written notice shall occur, the Corporation shall promptly give written notice of such material change to each holder of shares of Series A, Series B, Series C, and Series D.

(g) No Impairment. Without obtaining such consent of the holders of Series A, Series B, Series C, and Series D as may be required under Section 5 hereof, the Corporation will not, by amendment of 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 to be observed or performed hereunder by the Corporation, but will at all times in good faith assist in the carrying out of all the provisions of this Section 3 and in the taking of all such action as may be necessary or appropriate in order to protect the conversion rights of the holders of Series A, Series B, Series C, and Series D against impairment.

(h) Reservation of Stock Issuable Upon Conversion. The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of Series A, Series B, Series C, and Series D, such number of its shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of Series A, Series B, Series C, and Series D; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of Series A, Series B, Series C, and Series D, the Corporation will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purpose.

(i) Special Adjustment for Holders of Series B. If the Company issues or adjusts the Series C preferred stock, following the issuance of the Series A and Series B at an effective issuance less than \$1.00 per share or if the effective price of the Series C is subsequently adjusted to be less than \$1.00 per share of the Series C (the issuance price or effective price called the "Series C Effective Price"), an adjustment to the number of shares of Series B will be triggered, and the total number of Series B shares will be increased as if the Original Series B Price was fifty percent (50%) of the Series C Effective Price, subject to an effective floor price which will never be less than \$0.20. The Series C Effective Price, including consideration for the value of warrants or other securities or consideration offered to the holders of the Series C preferred stock, will be determined by the Board of Directors in the good faith exercise of its reasonable business judgment. Accordingly, each holder of Series B shall receive a number of additional shares of Series B, which when added to the shares of Series B held by such holder immediately prior to the triggering of this Special Adjustment, equals the total number of shares of Series B to which such holder of Series B is entitled, in the aggregate, as a result of this Special Adjustment. The total number of shares of Series B to which such holder of Series B is entitled, in the aggregate, as a result of this Special Adjustment, is calculated using

the following formula: the number of shares of Series B held by such holder immediately prior to the triggering of the adjustment is multiplied by a fraction, the numerator of which is \$0.50 and the denominator of which is the greater of fifty percent (50%) of the Series C Effective Price or \$0.20.

(ii) *Special Adjustment for Holders of Series C.* If the Company issues or adjusts the Series D preferred stock, following the issuance of the Series A, Series B, and Series C, at an effective issuance less than \$1.50 per share or if the effective price of the Series D is subsequently adjusted to be less than \$1.50 per share of the Series D (the issuance price or effective price called the “Series D Effective Price”), an adjustment to the number of shares of Series C will be triggered, and the total number of Series C shares will be increased as if the Original Series C Price was two thirds (2/3rds) of the Series D Effective Price, subject to an effective floor price which will never be less than \$0.30. The Series D Effective Price, including consideration for the value of warrants or other securities or consideration offered to the holders of the Series D preferred stock, will be determined by the Board of Directors in the good faith exercise of its reasonable business judgment. Accordingly, each holder of Series C shall receive a number of additional shares of Series C, which when added to the shares of Series C held by such holder immediately prior to the triggering of this Special Adjustment, equals the total number of shares of Series C to which such holder of Series C is entitled, in the aggregate, as a result of this Special Adjustment. The total number of shares of Series C to which such holder of Series C is entitled, in the aggregate, as a result of this Special Adjustment, is calculated using the following formula: the number of shares of Series C held by such holder immediately prior to the triggering of the adjustment is multiplied by a fraction, the numerator of which is \$1.00 and the denominator of which is the greater of two thirds (2/3rds) of the Series D Effective Price or \$0.30.

(iii) *Special Adjustment for Holders of Series D.* If the Company issues Series E preferred stock, following the issuance of the Series A, Series B, Series C, and Series D, at an effective issuance less than \$2.50 per share or if the effective price of the Series E is subsequently adjusted to be less than \$2.50 per share of the Series E (the issuance price or effective price called the “Series E Effective Price”), an adjustment to the number of shares of Series D will be triggered, and the total number of Series D shares will be increased as if the Original Series D Price was eighty percent (80%) of the Series E Effective Price, subject to an effective floor price which will never be less than \$0.30. The Series E Effective Price, including consideration for the value of warrants or other securities or consideration offered to the holders of the Series E preferred stock, will be determined by the Board of Directors in the good faith exercise of its reasonable business judgment. Accordingly, each holder of Series D shall receive a number of additional shares of Series D, which when added to the shares of Series D held by such holder immediately prior to the triggering of this Special Adjustment, equals the total number of shares of Series D to which such holder of Series D is entitled, in the aggregate, as a result of this Special Adjustment. The total number of shares of Series D to which such holder of Series D is entitled, in the aggregate, as a result of this Special Adjustment, is calculated using the following formula: the number of shares of Series D held by such holder immediately prior to the triggering of the adjustment is multiplied by a fraction, the numerator of which is \$2.00 and the denominator of which is the greater of eighty percent (80%) of the Series E Effective Price or \$0.30.

4. Voting Rights. Each holder of Series A, Series B, Series C, and Series D 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 Series A, Series B, Series C, or Series D could then be converted and, except as otherwise required by law or as set forth herein, shall have voting rights and powers equal to the voting rights and powers of the Common Stock. Each holder of Series A, Series B, Series C, and Series D shall be entitled to notice of any stockholders' meeting in accordance with the Bylaws of the Corporation and shall be entitled to vote with the holders of Common Stock with respect to any matter upon which holders of Common Stock have the right to vote, except as otherwise provided herein or those matters required by law to be submitted to a class vote. *Cumulative voting for the election of directors of the Corporation shall not be permitted.*

5. Protective Provisions.

(a) So long as any shares of Series A are outstanding (as adjusted for any Recapitalization Event), the Corporation shall not, without first obtaining the affirmative vote or written consent of the holders of a majority of the voting power represented by the then outstanding shares of Series A, voting together as a class, (i) modify the rights, preferences, privileges or restrictions of the Series A so as to adversely affect the Series A; (ii) increase the total number of authorized shares of Series A; nor (iii) authorize or create any other equity security having a preference over, or on a parity with, the Series A with respect to dividends, liquidation, redemption or voting.

(b) So long as any shares of Series B are outstanding (as adjusted for any Recapitalization Event), the Corporation shall not, without first obtaining the affirmative vote or written consent of the holders of a majority of the voting power represented by the then outstanding shares of Series B, voting together as a class, (i) modify the rights, preferences, privileges or restrictions of the Series B so as to adversely affect the Series B; (ii) increase the total number of authorized shares of Series B; nor (iii) authorize or create any other equity security having a preference over, or on a parity with, the Series B with respect to dividends, liquidation, redemption or voting.

(c) So long as any shares of Series C are outstanding (as adjusted for any Recapitalization Event), the Corporation shall not, without first obtaining the affirmative vote or written consent of the holders of a majority of the voting power represented by the then outstanding shares of Series C, voting together as a class, (i) modify the rights, preferences, privileges or restrictions of the Series C so as to adversely affect the Series C; (ii) increase the total number of authorized shares of Series C; nor (iii) authorize or create any other equity security having a preference over, or on a parity with, the Series C with respect to dividends, liquidation, redemption or voting.

(d) So long as any shares of Series D are outstanding (as adjusted for any Recapitalization Event), the Corporation shall not, without first obtaining the affirmative vote or written consent of the holders of a majority of the voting power represented by the then outstanding shares of Series D, voting together as a class, (i) modify the rights, preferences, privileges or restrictions of the Series D so as to adversely affect the Series D; (ii) increase the total number of authorized shares of Series D; nor (iii) authorize or create any other equity

security having a preference over, or on a parity with, the Series D with respect to dividends, liquidation, redemption or voting.

6. Status of Converted Stock. In the event any shares of Series A, Series B, Series C, or Series D shall be converted pursuant to Section 3 hereof, or otherwise acquired by the Corporation, the shares so converted shall be canceled and shall not be issuable by the Corporation. This Amended and Restated Certificate of Incorporation shall be appropriately amended to effect the corresponding reduction in the Corporation's authorized capital stock.

7. Registered Owners. The Corporation shall be entitled to treat the person in whose name any share of its stock is registered as the owner thereof for all purposes and shall not be bound to recognize any equitable or other claim to, or interest in, such share on the part of any other person, whether or not the Corporation shall have notice thereof, except as expressly provided by applicable law.

ARTICLE VI

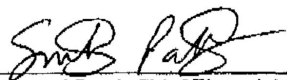
The business and affairs of the Corporation shall be managed under the direction of its Board of Directors. In furtherance, and not in limitation, of the powers conferred by the laws of the State of Delaware, the Board of Directors is expressly authorized to make, alter, amend or repeal the By-Laws of the Corporation and to exercise all such powers and do all such acts as may be exercised by the Corporation, subject to the provisions of the laws of the State of Delaware.

ARTICLE VII

To the fullest extent permitted by the DGCL, as the same exists or may hereafter be amended, 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. Any amendment or repeal of this Article VII shall not adversely affect any right or protection of a director of the Corporation existing hereunder in respect of any act or omission occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware shall be amended, to authorize corporate action further eliminating or limiting the liability of directors, then a director of the Corporation, in addition to the circumstances in which he is not liable immediately prior to such amendment, shall be free of liability to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended.

To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers, employees and other agents of the Corporation and any other persons to which Delaware law permits the Corporation to provide indemnification), through Bylaw provisions, agreements with any such director, officer, employee or other agent or other person, vote of stockholders, or disinterested directors, or otherwise, in the amount permitted in excess of the indemnification and advancement otherwise permitted by the DGCA, subject only to limits created by applicable Delaware law (statutory or nonstatutory), with respect to actions for breach of duty of a corporation, its stockholder and others.

IN WITNESS WHEREOF, said Corporation has caused this certificate to be signed this
19th day of April, 2011


By: Snehal Patel, Chief Financial Officer
and Secretary

**State of Delaware**

SECRETARY OF STATE
DIVISION OF CORPORATIONS
P.O. BOX 898
DOVER, DELAWARE 19903

8287537
SNEHAL PATEL
2311 SPARTAN TRAIL
SUGAR LAND, TX 77479

07-05-2019

DESCRIPTION	AMOUNT
4211497 - GREENWICH LIFESCIENCES, INC.	
4100 Plain Copy	
Plain Copy Fee	\$10.00
Expedite Fee, 24 Hour	\$20.00
4211497 - GREENWICH LIFESCIENCES, INC.	
4100 Plain Copy - 1 Copies	
TOTAL CHARGES	\$30.00
TOTAL PAYMENTS	\$30.00
BALANCE	\$0.00

**STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF INCORPORATION**

The corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify:

FIRST: That at a meeting of the Board of Directors of

Norwell, Inc.

resolutions were duly adopted setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable and calling a meeting of the stockholders of said corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended by changing the Article thereof numbered "Article I" so that, as amended, said Article shall be and read as follows:

The name of this Corporation is
Greenwich Life Sciences, Inc.

SECOND: That thereafter, pursuant to resolution of its Board of Directors, a special meeting of the stockholders of said corporation was duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of the amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said corporation has caused this certificate to be signed this 2nd day of March, 2018.

By: _____

Authorized Officer

Title: _____

Vice President

Name: _____

Snehal Patel

Print or Type

PAGE 1 of 1

Service Request# 20196927944

**State of Delaware**SECRETARY OF STATE
DIVISION OF CORPORATIONS
P.O. BOX 898
DOVER, DELAWARE 199038304691
GREENWICH LIFESCIENCES
2311 SPARTAN TRAIL
SUGAR LAND, TX 77479

09-12-2019

DESCRIPTION	AMOUNT
4211497 - GREENWICH LIFESCIENCES, INC. 02405 Amendment Stock	
Amendment Fee	\$30.00
Receiving/Indexing	\$115.00
Surcharge Assessment-New Castle County	\$6.00
Page Assessment-New Castle County	\$27.00
Data Entry Fee	\$5.00
Court Municipality Fee, Wilm.	\$20.00
Expedite Fee, 24 Hour	\$100.00
TOTAL CHARGES	\$303.00
TOTAL PAYMENTS	\$303.00
BALANCE	\$0.00

**STATE OF DELAWARE CERTIFICATE OF AMENDMENT OF
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: That the Board of Directors of the Corporation has duly adopted resolutions (i) authorizing the Corporation to execute and file with the Secretary of State of the State of Delaware this Certificate of Amendment (this "Amendment") of the Corporation's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"); (ii) to increase the total number of authorized capital of the Corporation; (iii) to increase the total number of authorized common stock; to (iv) increase the total number of authorized Series D Preferred Stock; (v) declaring this Amendment to be advisable, submitted to and considered by the stockholders of the Corporation entitled to vote thereon for approval by the affirmative vote of such stockholders in accordance with the terms of the Corporation's Certificate of Incorporation and Section 242 of the General Corporation Law of the State of Delaware (the "DGCL"); and (vi) recommending this Amendment for approval by the stockholders of the Corporation.

SECOND: That this Amendment was duly adopted in accordance with the terms of the Certificate of Incorporation and the provisions of Section 242 of the DGCL by the stockholders of the Corporation.

THIRD: Article IV of the Certificate of Incorporation shall be amended and restated in its entirety as follows:

"The total number of shares of all classes of capital stock which the Corporation shall have the authority to issue is One Hundred Six Million Seven Hundred Ninety Five Thousand (106,795,000) shares which shall be divided into the following classes:

(a) One Hundred Million (100,000,000) shares of Common Stock with a par value of \$0.001 per share ("Common Stock");

(b) Four Million Two Hundred Thousand (4,200,000) shares of Series A Preferred Stock with a par value of \$0.001 per share ("Series A");

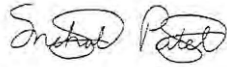
(c) Three Hundred Ninety Thousand (390,000) shares of Series B Preferred Stock with a par value of \$0.001 per share ("Series B");

(d) Two Hundred Five Thousand (205,000) shares of Series C Preferred Stock with a par value of \$0.001 per share ("Series C"); and

(c) Two Million (2,000,000) shares of Series D Preferred Stock with a par value of \$0.001 per share ("Series D")."

IN WITNESS WHEREOF, said corporation has caused this certificate to be signed this day 9th day of September, 2019.

By:

A handwritten signature in cursive script, appearing to read "Snehal Patel", is written over a horizontal line.

Authorized Officer

Title: Chief Executive Officer

Name: Snehal Patel

NORWELL, INC.

AMENDED AND RESTATED BYLAWS

July 23, 2010

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ARTICLE I-CORPORATE OFFICES

1.1 Registered Office. The registered office of the Corporation shall be in the City of Dover, County of Kent, State of Delaware. The name of the registered agent of the Corporation at such location is The Company Corporation.

1.2 Other Offices. The Board of Directors may at any time establish other offices at any place or places where the Corporation is qualified to do business.

ARTICLE 2-MEETINGS OF STOCKHOLDERS

2.1 Place of Meetings. Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board of Directors. In the absence of any such designation, stockholders’ meetings shall be held at the registered office of the Corporation.

2.2 Annual Meeting. The annual meeting of stockholders shall be held on such date, time and place, either within or without the State of Delaware as may be designated by resolution of the Board of Directors each year. At the meeting, directors shall be elected and any other proper business may be transacted.

2.3 Special Meetings. A special meeting of the stockholders may be called at anytime by the Board of Directors, the Chairman of the Board, the president or by one or more stockholders holding shares in the aggregate entitled to cast not less than ten percent of the votes at that meeting. If a special meeting is called by any person or persons other than the Board of Directors, the President or the Chairman of the Board the request shall be in writing, specifying the time of such meeting and the general nature of the business proposed to be transacted, and shall be delivered personally or sent by registered mail or by telegraphic or other facsimile transmission to the Chairman of the Board, the President, any Vice President, or the Secretary of the Corporation. No business may be transacted at such special meeting otherwise than specified in such notice. The officer receiving the request shall cause notice to be promptly given to the stockholders entitled to vote, in accordance with the provisions of Sections 2.4 and 2.5 of this Article II, that a meeting will be held at the time requested by the person or persons calling the meeting, not less than thirty-five (35) nor more than sixty (60) days after the receipt of the request. If the notice is not given within twenty (20) days after the receipt of the request, the person or persons requesting the meeting may give the notice. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board of Directors maybe held.

2.4 Notice of Stockholders’ Meetings. All notices of meetings with stockholders shall be in writing and shall be sent or otherwise given in accordance with Section 2.5 of these Bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place (if any), date and hour of the meeting, and in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.5 Manner of Giving Notice; Affidavit of Notice. Written notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders may be given by electronic mail or other electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law. An affidavit of the secretary or an assistant secretary or of the transfer 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.

2.6 Quorum. The holders of a majority of the shares of stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise provided by statute or by the certificate of incorporation. If, however, such quorum is not present or represented at any meeting of the stockholders, then either (a) the chairman of (the meeting or (b) holders of a majority of the shares of stock entitled to vote who are present, in person or by proxy, shall have power to adjourn the meeting to another place (if any), date or time.

2.7 Adjourned Meeting; Notice. When a meeting is adjourned to another place (if any), date or time, unless these Bylaws otherwise require, notice need not be given of the adjourned meeting if the time and place (if any) thereof and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present 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 that might have been transacted at the original meeting. If the adjournment is for more than 30 days, or if, after the adjournment a new record date is fixed for the adjourned meeting, notice of the place (if any), date and time of the adjourned meeting 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 shall be given to each stockholder of record entitled to vote at the meeting.

2.8 Organization; Conduct of Business. (a) Such person as the Board of Directors may have designated or, in the absence of such a person, the President of the Corporation of, in his or her absence, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present, in person or by proxy, shall call to order any meeting of the stockholders and act as Chairman of the meeting. In the absence of the Secretary of the Corporation, the Secretary of the meeting shall be such person as the Chairman of the meeting appoints. (b) The Chairman of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including the manner of voting and the conduct of business. The date and time of opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting.

2.9 Voting. The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.12 of these Bylaws, subject to the provisions of Sections 217 and 218 of the General Corporation Law of Delaware (relating to voting rights of fiduciaries, pledgors and joint owners of stock and to voting trusts and other voting agreements). Except as maybe otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder. All elections shall be determined by a "plurality" of the votes cast, and except as otherwise required by law; all other matters shall be decided by a majority of the votes cast affirmatively or negatively.

2.10 Waiver of Notice. Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these Bylaws, a written waiver thereof, signed by the person entitled to notice, or waiver by electronic mail or other electronic transmission by such person, 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 need be specified in any written waiver of notice, or any waiver of notice by electronic transmission, unless so required by the certificate of incorporation or these Bylaws.

2.11 Stockholder Action by Written Consent without a Meeting. Unless otherwise provided in the certificate of incorporation, any action required to be taken at any annual or special meeting of stockholders of the Corporation, or any action that may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice, and without a vote if a consent in writing and setting forth the action so taken, is (i) signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted, and (ii) delivered to the Corporation in accordance with Section 228(a) of the Delaware General Corporation Law. Every written consent shall bear the date of signature of each stockholder who signs the consent and no written consent shall be effective to take the corporate action referred to therein unless, within 60 days of the date the earliest dated consent is delivered to the Corporation, a written consent or consents signed by a sufficient number of holders to take action are delivered to the Corporation in the manner prescribed in this Section. A telegram, cablegram, electronic mail or other electronic transmission consenting to an action to be taken and transmitted by a stockholder or proxy holder, or by a person or persons authorized to act for a stockholder or proxy holder, shall be deemed to be written, signed and dated for purposes of this Section to the extent permitted by law. Any such consent shall be delivered in accordance with Section 228 (d) (I) of the Delaware General Corporation Law. Any copy, facsimile or other reliable reproduction of a consent in writing maybe substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing (including by electronic mail or other electronic transmission as permitted by law). If the action which is consented to is such as would have required the filing of a certificate under any section of the General Corporation Law of Delaware if such action had been voted on by stockholders at a meeting thereof; then the certificate filed under such section shall state, in lieu of any statement required by such section concerning any vote of stockholders, that written notice and written consent have been given as provided in Section 228 of the General Corporation Law of Delaware.

2.12 Record Date for Stockholder Notice; Voting; Giving Consents. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or 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 of Directors may fix, in advance, a record date, which shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action.

If the Board of Directors does not so fix a record date:

(a) The record date for determining stockholders entitled to notice of or 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.

(b) The record date for determining stockholders entitled to consent to corporate action in writing without a meeting, when no prior action by the Board of Directors is necessary, shall be the day on which the first written consent (including consent by electronic mail or other electronic transmission as permitted by law) is delivered to the Corporation.

(c) The record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

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, if such adjournment is for thirty(30) days or less; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

2.13 Proxies. Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for such stockholder by an instrument in writing or by an electronic transmission permitted by law filed with the secretary of the Corporation, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, facsimile, electronic or telegraphic transmission or otherwise) by the stockholder or the stockholder's attorney-in-fact. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212(e) of the General Corporation Law of Delaware.

ARTICLE-III DIRECTORS

3.1 Powers. Subject to the provisions of the General Corporation Law of Delaware and any limitations in the certificate of incorporation or these Bylaws relating to action required to be approved by the stockholders or by the outstanding shares, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board of Directors.

3.2 Number of Directors. Upon the adoption of these bylaws, the number of directors constituting the entire Board of Directors shall be three (3). Thereafter, this number may be changed by a resolution of the Board of Directors or of the stockholders, subject to Section

3.4 of these Bylaws. No reduction of the authorized number of directors shall have the effect of removing any director before such director's tenor of officer expires.

3.3 Election, Qualification and Term of Office of Directors. Except as provided in Section

3.4 of these Bylaws, and unless otherwise provided in the certificate of incorporation or in a voting agreement then in effect directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting. Directors need not be stockholders unless required by the certificate of incorporation or these Bylaws, wherein other qualifications for directors may be prescribed. Each director, including a director elected to fill a vacancy, shall hold office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Unless otherwise specified in the certificate of incorporation, elections of directors need not be by written ballot.

3.4 Resignation and Vacancies. Any director may resign at any time upon written notice to the attention of the Secretary of the corporation. When one or more directors resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies. Unless otherwise provided in the certificate of incorporation or these Bylaws:

(a) Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. (b) Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected. If at any time, by reason of death or resignation or other cause, the Corporation should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these Bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as provided in Section 211 of the General Corporation Law of Delaware. If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board (as constituted immediately prior to any such increase), then the Court of Chancery may, upon application of any stockholder or stockholders holding at least 10% of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the General Corporation Law of Delaware as applicable.

3.5 Place of Meetings; Meetings by Telephone. The Board of Directors of the Corporation may hold meetings, both regular and special, either within or outside the State of Delaware. Unless otherwise restricted by the certificate of incorporation or these Bylaws, members of the Board of Directors, or any committee designated by the Board of Directors, may participate in a meeting of the Board of Directors, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and at such place as shall from time to time be determined by the board.

3.7 Special Meetings; Notice. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the chairman of the board, the president, any vice president, the secretary or any two directors. Notice of the time and place of special meetings shall be delivered personally or by telephone to each director or sent by first-class mail facsimile, electronic transmission; or telegram, charges prepaid, addressed to each director at that directors address as it is shown on the records of the Corporation. If the notice is mailed, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. If the notice is delivered personally or by facsimile, electronic transmission, telephone or telegram, it shall be delivered at least 48 hours before the time of the holding of the meeting. Any oral notice given personally or by telephone may be communicated either to the director or to a person at the office of the director who the person giving the notice has reason to believe will promptly communicate it to the director. The notice need not specify the purpose of the meeting. The notice need not specify the place of the meeting, if the meeting is to be held at the principal executive office of the Corporation. Unless otherwise indicated in the notice thereof, any and all business maybe transacted at a special meeting.

3.8 Quorum. At all meetings of the Board of Directors, a majority of the total number of directors shall constitute quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute or by the certificate of incorporation. If a quorum is not present at any meeting of the Board of Directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the requisite quorum for that meeting.

3.9 Waiver of Notice. Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these Bylaws, a written waiver thereto signed by the person entitled to notice, or waiver by electronic mail or other electronic transmission by such person, 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 directors, or members of a committee of directors, need be specified in any written waiver of notice unless so required by the certificate of incorporation or these Bylaws.

3.10 Board Action by Written Consent without a Meeting. Unless otherwise restricted by the certificate of incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, 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 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 copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and any purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

3.11 Fees and Compensation of Directors. Unless otherwise restricted by the certificate of incorporation or these Bylaws, the Board of Directors shall have the authority to fix the compensation of directors. No such compensation shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefore.

3.12 Approval of Loans to Officers. The Corporation may lend money to, or guarantee any obligation of, or otherwise assist any officer or other employee of the Corporation or of its subsidiary, including any officer or employee who is a director of the Corporation or its subsidiary, whenever, in the judgment of the directors, such loan, guaranty or assistance may reasonably be expected to benefit the Corporation. The loan, guaranty or other assistance may be with or without interest and may be unsecured, or secured in such manner as the Board of Directors shall approve, including, without limitation, a pledge of shares of stock of the Corporation. Nothing in this section shall be deemed to deny, limit or restrict the powers of guaranty or warranty of the Corporation at common law or under any statute.

3.13 Removal of Directors. Unless otherwise restricted by statute, by the certificate of incorporation or by these Bylaws, any director or the entire Board of Directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors. No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

3.14 Chairman of the Board of Directors. The Corporation may also have, at the discretion of the Board of Directors, a chairman of the Board of Directors who shall not be considered an officer of the Corporation.

ARTICLE IV-COMMITTEES

4.1 Committees of Directors. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. 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 of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors, or in these Bylaws, shall have and may exercise all the powers and authority of the Board of Directors 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 matters: (i) approving or adopting, or recommending to the stockholders, any action or matter expressly required by the General Corporate Law of Delaware to be submitted to stockholders for approval or (ii) adopting, amending or repealing any Bylaw of the Corporation.

4.2 Committee Minutes. Each committee shall keep regular minutes of its meetings and report the same to the Board of Directors when required.

4.3 Meetings and Action of Committees. Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of Section 3.5 (place of meetings and meetings by telephone), Section 3.6 (regular meetings), Section 3.7 (special meetings and notice), Section 3.8 (quorum), Section 3.9(waiver of notice) and Section 3.10(action without a meeting) of these Bylaws, with such changes in the context of such provisions as are necessary to substitute the committee and its members for the Board of Directors and its members; provided, however, that the time of regular meetings of committees may be determined either by resolution of the Board of Directors or by resolution of the committee, that special meetings of committees may also be called by resolution of the Board of Directors and that notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board of Directors may adopt rules for the government of any committee not inconsistent with the provisions of these Bylaws.

ARTICLE V-OFFICERS

5.1 Officers. The officers of the Corporation shall be a chief executive officer, a president, a secretary, and a chief financial officer. The Corporation may also have, at the discretion of the Board of Directors, one or more vice presidents, one or more assistant secretaries, one or more assistant treasurers, and any such other officers as may be appointed in accordance with the provisions of Section 5.3 of these Bylaws. Any number of offices may be held by the same person.

5.2 Appointment of Officers. The officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Sections 5.3 or 5.5 of these Bylaws, shall be appointed by the Board of Directors, subject to the rights, if any, of an officer under any contract of employment.

5.3 Subordinate Officers. The Board of Directors may appoint, or empower the chief executive officer or the president to appoint, such other officers and agents as the business of the Corporation may require, each of whom shall hold office for such period, have such authority, and performs such duties as are provided in these Bylaws or as the Board of Directors may from time to time determine.

5.4 Removal and Resignation Officers. Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the Board of Directors at any regular or special meeting of the board, or except in the case of an officer chosen by the Board of Directors, by any officer upon whom the power of removal is conferred by the Board of Directors. Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice; and, unless otherwise specified in that notice, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices. Any vacancy occurring in any office of the Corporation shall be filled by the Board of Directors.

5.6 Chief Executive Officer. Subject to such supervisory powers, if any, as may be given by the Board of Directors to the chairman of the board, if any, the chief executive officer of the Corporation (if such an officer is appointed) shall, subject to the control of the Board of Directors, have general supervision, direction, and control of the business and the officers of the Corporation. He or she shall have the general powers and duties of management usually vested in the office of chief executive officer of a Corporation and shall have such other powers and duties as may be prescribed by the Board of Directors or these Bylaws.

5.7 President. Subject to such supervisory powers, if any, as may be given by the Board of Directors to the chairman of the board (if any) or the chief executive officer, the president shall have general supervision, direction, and control of the business and other officers of the Corporation. He or she shall have the general powers and duties of management usually vested in the office of president of a Corporation and such other powers and duties as may be prescribed by the Board of Directors or these Bylaws.

5.8 Vice Presidents. In the absence or disability of the chief executive officer and president, the vice presidents, if any, in order of their rank as fixed by the Board of Directors or, if not ranked, a vice president designated by the Board of Directors, shall perform all the duties of the president and when so acting shall have all the powers of and be subject to all the restrictions upon, the president. The vice presidents shall have such other powers and perform such other duties as from time to time may be prescribed for them respectively by the Board of Directors, these Bylaws, the president or the chairman of the board.

5.9 Secretary. The secretary shall keep or cause to be kept, at the principal executive office of the Corporation or such other place as the Board of Directors may direct, a book of minutes of all meetings and actions of directors, committees of directors, and stockholders. The minutes shall show the time and place of each meeting, the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings, and the proceedings thereof. The secretary shall keep, or cause to be kept, at the principal executive office of the Corporation or at the office of the Corporation's transfer agent or registrar as determined by resolution of the Board of Directors, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares, and the number and date of cancellation of every certificate surrendered for cancellation. The secretary shall give, or cause to be given, notice of all meetings of the stockholders and of the Board of Directors required to be given by law or by these Bylaws. He or she shall keep the seal of the Corporation, if one be adopted, in safe custody and shall have such other powers and perform such other duties as may be prescribed by the Board of Directors or by these Bylaws.

5.10 Chief Financial Officer. The chief financial officer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the Corporation, including accounts of its assets, liabilities, receipts, disbursements gains, losses, and capital retained earnings, and shares. The books of account shall at all reasonable times be open to inspection by any director. The chief financial officer shall deposit all moneys and other valuables in the name and to the credit of the Corporation with such depositories as may be designated by the Board of Directors. He or she shall disburse the funds of the Corporation as may be ordered by the Board of Directors, shall render to the president, the chief executive officer, or the directors, upon request, an account of all his or her transactions as chief financial officer and of the financial condition of the Corporation, and shall have other powers and perform such other duties as may be prescribed by the Board of Directors or the bylaws.

5.11 Representation of Shares of Other Corporations. The chairman of the board, the chief executive officer, the president, any vice president, the chief financial officer, the secretary or assistant secretary of this Corporation, or any other person authorized by the Board of Directors or the chief executive officer or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this Corporation all rights incident to any and all shares of any other Corporation or Corporations standing in the name of this Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by the person having such authority.

5.12 Authority and Duties of Officers. In addition to the foregoing authority and duties, all officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be designated from time to time by the Board of Directors or the stockholders.

ARTICLE VI-INDEMNIFICATION OF DIRECTORS, OFFICERS, EMPLOYEES, AND OTHER AGENTS

6.1 Indemnification of Directors and Officers. The Corporation shall, to the maximum extent and in the manner permitted by the General Corporation Law of Delaware, indemnify each of its directors and officers against expenses (including attorneys' fees) judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the Corporation. For purposes of this Section 6.1, a "director" or "officer" of the Corporation includes any person (a) who is or was a director or officer of the Corporation, (b) who is or was serving at the request of the Corporation as a director or officer of another Corporation, partnership, joint venture, trust or other enterprise, or (c) who was a director or officer of a Corporation which was a predecessor Corporation of the Corporation or of another enterprise at the request of such predecessor Corporation.

6.2 Indemnification of Others. The Corporation shall have the power, to the maximum extent and in the manner permitted by the General Corporation Law of Delaware, to indemnify each of its employees and agents (other than directors and officers) against expenses (including attorneys, fees), judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the Corporation. For purposes of this Section 6.2, an "employee" or "agent" of the Corporation (other than a director or officer) includes any person (a) who is or was an employee or agent of the Corporation, (b) who is or was serving at the request of the Corporation as an employee or agent of another Corporation, partnership, joint venture, trust or other enterprise, or (c) who was an employee or agent of a Corporation which was a predecessor Corporation of the Corporation or of another enterprise at the request of such predecessor Corporation.

6.3 Payment of Expenses In Advance. Expenses incurred in defending any action or proceeding for which indemnification is required pursuant to Section 6.1 or for which indemnification is permitted pursuant to Section 6.2 following authorization thereof by the Board of Directors shall be paid by the Corporation in advance of the final disposition of such action or proceeding upon receipt of an undertaking by or on behalf of the indemnified party to repay such amount if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that the indemnified party is not entitled to be indemnified as authorized in this Article VI.

6.4 Indemnity Not Exclusive. The indemnification provided by this Article VI shall not be deemed exclusive of any other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, but the Corporation shall not be bound to action in an The secretary shall keep or cause to be kept, at the principal executive office of the Corporation or such other place as the Board of Directors may direct, a book of minutes of all meetings and actions of directors, committees of directors, and stockholders. The minutes shall show the time and place of each meeting, the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings, and the proceedings thereof. The secretary shall keep, or cause to be kept, at the principal executive office of the Corporation or at the office of the Corporation's transfer agent or registrar as determined by resolution of the Board of Directors, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares, and the number and date of cancellation of every certificate surrendered for cancellation. and as to action in another capacity while holding such office, to the extent that such additional rights to indemnification are authorized in the certificate of incorporation

6.5 Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer; employee or agent of the Corporation was serving at the request of the Corporation as a director, officer, employee or agent of another Corporation. Partnership, joint venture, trust or other enterprise against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of the General Corporation Law of Delaware.

6.6 Conflicts. No indemnification or advance shall be made under this Article VI, except where such indemnification or advance is mandated by law or the order, judgment or decree of any court of competent jurisdiction, in any circumstance where it appears:

(a) That it would be inconsistent with a provision of the certificate of incorporation, these Bylaws, a resolution of the stockholders or an agreement in effect at the time of the accrual of the alleged cause of the action asserted in the proceeding in which the expenses were incurred or other amounts were paid, which prohibits or otherwise limits indemnification; or

(b) That it would be inconsistent with any condition expressly imposed by a court in approving a settlement.

ARTICLE VII-RECORDS AND REPORTS

7.1 Maintenance and Inspection of Records. The Corporation shall, either at its principal executive offices or at such place or places as designated by the Board Directors, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these Bylaws as amended to date, accounting books, and other records. Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the Corporation's stock ledger, a list of its stockholders, and its other books and records and to make copies or extracts therefrom. A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent is the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent to so act on behalf of the stockholder. The demand under oath shall be directed to the Corporation at its registered office in Delaware or at its principal place of business. A complete list of stockholders entitled to vote at any meeting of stockholders, arranged in alphabetical order for each class of stock and showing the address of each such stockholder and the number of shares registered in each such stockholder's name, shall be open to the examination of any such stockholder for a period or at least ten (10) days prior to the meeting in the manner provided by law. The stock list shall also be open to the examination of any stockholder during the whole time of the meeting as provided by law. This list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

7.2 Inspection by Directors. Any director shall have the right to examine the Corporation's stock ledger, a list of its stockholders, and its other books and records for a purpose reasonably related to his or her position as a director. The Court of Chancery is hereby vested with the exclusive jurisdiction to determine whether a director is entitled to the inspection sought. The Court may summarily order the Corporation to permit the director to inspect any and all books and records, the stock ledger, and the stock list and to make copies or extracts therefrom. The Court may, in its discretion, prescribe any limitations or conditions with reference to the inspection, or award such other and further relief as the Court may deem just and proper.

ARTICLE VIII-GENERAL MATTERS

8.1 Checks. From time to time, the Board of Directors shall determine by resolution which person or persons may sign or endorse all checks, drafts, other orders for payment of money, notes or other evidences of indebtedness that are issued in the name of or payable to the Corporation, and only the persons so authorized shall sign or endorse those instruments.

8.2 Execution of Corporate Contracts and Instruments. The Board of Directors, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of or on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

8.3 Stock Certificates; Partly Paid Shares. The shares of a Corporation shall be represented by certificates, provided that the Board of Directors of the Corporation 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. Notwithstanding the adoption of such a resolution by the Board of Directors, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the Corporation by the chairman or vice-chairman of the Board of Directors, or the, chief executive officer, president or vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of such Corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue. The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefore. Upon the face or back of each stock certificate issued to represent any such partly paid shares, upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefore and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

8.4 Special Designation Certificates. If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications limitations or restrictions of such preferences and/or rights.

8.5 Lost Certificates. Except as provided in this Section 8.5, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation and cancelled at the same time. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate previously 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 the 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.

8.6 Construction; Definitions. Unless the context requires otherwise, the general provisions, rules of construction and definitions in the Delaware General Corporation Law shall govern the construction of these Bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a Corporation and a natural person.

8.7 Dividends. The directors of the Corporation, subject to any restrictions contained in (a) the General Corporation Law of Delaware or (b) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property, or in shares of the Corporation's capital stock. The directors of the Corporation may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

8.8 Fiscal Year. The fiscal year of the Corporation shall be fixed by resolution of the Board of Directors and may be changed by the Board of Directors.

8.9 Seal. The Corporation may adopt a corporate seal, which may be altered at its pleasure, and may use the same by causing it or a facsimile thereto: to be impressed or affixed or in any other manner reproduced.

8.10 Right of First Refusal. In the event that any stockholder of any capital stock of the Corporation proposes to make a sale of capital stock other than in a public offering, then such stockholder shall provide notice of such intent, including the name, address and occupation of the proposed bona fide purchaser, and the price, to the Corporation. Upon receipt of such notice, the Corporation shall have thirty (30) days in which to elect to buy all of the proposed offer of such capital stock at the same price. In the event that the Corporation makes such an election, the sale shall be completed within sixty (60) days of the date that notice of the proposed sale was received from the stockholder by the Corporation. In the event that the Corporation elects not to purchase the capital stock offered by the stockholder, notice of such decision shall be provided by the Corporation to the offering stockholder within thirty (30) days of the date that notice of the proposed sale was received from the stockholder by the Corporation. The sale, as initially proposed by the offering stockholder, may then take place if completed within thirty (30) days from the date of receipt of such notice that the Corporation has elected not to purchase the offered shares of capital stock and if satisfactory documentation is provided by the offering stockholder that the sale is exempt from the registration provisions of applicable federal and state securities laws. If such sale and transfer does not occur within such thirty (30) days, then any other proposed sale of the offered capital stock shall be deemed subject to the time and notice restrictions imposed by this Section 8.10, and these time and notice restrictions shall begin and apply again as if no other notice had been given.

8.11 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, assignation or authority to transfer, and any additional documentation required by law or agreement with the Corporation, it shall be the duty of the Corporation to issue a new certificate to the person entitled thereto, cancel the old certificate, and record the transaction in its books.

8.12 Stock Transfer Agreements. The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the General Corporation Law of Delaware.

8.13 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner, shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof except as otherwise provided by the laws of Delaware.

8.14 Facsimile Signatures. In addition to the provisions for use of facsimile signatures elsewhere specifically authorized in these Bylaws, facsimile signatures of any officer or officers of the Corporation may be used whenever and as authorized by the Board of Directors or a committee thereof.

ARTICLE IX-AMENDMENTS

The Bylaws of the Corporation may be adopted, amended or repealed by the stockholders entitled to vote; provided, however, that the Corporation may, in its certificate of incorporation, confer the power to adopt, amend or repeal Bylaws upon the directors. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal Bylaws.

GREENWICH LIFE SCIENCES, INC.
2019 EQUITY INCENTIVE PLAN
EFFECTIVE AS OF SEPTEMBER 30, 2019

GREENWICH LIFE SCIENCES, INC.

2019 EQUITY INCENTIVE PLAN

EFFECTIVE AS OF SEPTEMBER 30, 2019

SECTION 1. INTRODUCTION.

The Company's Board of Directors adopted the Greenwich Life Sciences, Inc. 2019 Equity Incentive Plan effective as of the Adoption Date subject to obtaining Company stockholder approval as provided in Section 15 below.

The purpose of the Plan is to promote the long-term success of the Company and the creation of stockholder value by offering Key Employees an opportunity to acquire a proprietary interest in the success of the Company, or to increase such interest, and to encourage such Key Employees to continue to provide services to the Company and to attract new individuals with outstanding qualifications.

The Plan seeks to achieve this purpose by providing for Awards in the form of Options (which may constitute Incentive Stock Options or Nonstatutory Stock Options), Stock Appreciation Rights, Restricted Stock Grants, Stock Units, Other Equity Awards and/or Cash Awards.

Capitalized terms shall have the meaning provided in Section 2 unless otherwise provided in this Plan or any related Award Agreement.

SECTION 2. DEFINITIONS. If a Participant's employment agreement or Award Agreement (or other written agreement executed by and between Participant and the Company) expressly includes defined terms that expressly are different from and/or conflict with the defined terms contained in this Plan then the defined terms contained in the employment agreement or Award Agreement (or other written agreement executed by and between Participant and the Company) shall govern and shall supersede the definitions provided in this Plan.

(a) **"Adoption Date"** means September 30, 2019.

(b) **"Affiliate"** means any entity other than a Subsidiary, if the Company and/or one or more Subsidiaries own not less than 50% of such entity.

(c) **"Award"** means any award of an Option, SAR, Restricted Stock Grant, Stock Unit, Other Equity Award or Cash Award under the Plan.

(d) **“Award Agreement”** means an agreement between the Company and a Participant evidencing the award of an Option, SAR, Restricted Stock Grant, Stock Unit, Other Equity Award or Cash Award as applicable.

(e) **“Board”** means the Board of Directors of the Company, as constituted from time to time.

(f) **“California Participant”** means a Participant whose Award was issued in reliance on Section 25102(o) of the California Corporations Code.

(g) **“Cash Award”** means, a cash incentive opportunity awarded under this Plan and which is (i) payable only in cash and is (ii) not an Option, SAR, Restricted Stock Grant, Stock Unit or Other Equity Award.

(h) **“Cashless Exercise”** means, to the extent that a Stock Option Agreement so provides and as permitted by applicable law and in accordance with any procedures established by the Committee, an arrangement whereby payment of some or all of the aggregate Exercise Price may be made all or in part by delivery of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company. Cashless Exercise may also be utilized to satisfy an Option’s tax withholding obligations as provided in Section 14(b).

(i) **“Cause”** means, with respect to a Participant, the occurrence of any of the following: (i) a conviction of a Participant for a felony crime or the failure of a Participant to contest prosecution for a felony crime, or (ii) a Participant’s misconduct, fraud, disloyalty or dishonesty (as such terms may be defined by the Committee in its sole discretion), or (iii) any unauthorized use or disclosure of confidential information or trade secrets by a Participant, or (iv) a Participant’s negligence, malfeasance, breach of fiduciary duties, neglect of duties, or (v) any material violation by a Participant of a written Company or Subsidiary or Affiliate policy or any material breach by a Participant of a written agreement with the Company or Subsidiary or Affiliate, or (vi) any other act or omission by a Participant that, in the opinion of the Committee, could reasonably be expected to adversely affect the Company’s or a Subsidiary’s or an Affiliate’s business, financial condition, prospects and/or reputation. In each of the foregoing subclauses (i) through (vi), whether or not a “Cause” event has occurred will be determined by the Committee in its sole discretion or, in the case of Participants who are directors or Officers or Section 16 Persons, the Board, each of whose determination shall be final, conclusive and binding. A Participant’s Service shall be deemed to have terminated for Cause if, after the Participant’s Service has terminated, facts and circumstances are discovered that would have justified a termination for Cause, including, without limitation, violation of material Company policies or breach of noncompetition, confidentiality or other restrictive covenants that may apply to the Participant.

(j) **“Change in Control”** means the occurrence of any of the following:

(i) The consummation of an acquisition, a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if more than 50% of the combined voting power of the continuing or surviving entity’s securities outstanding immediately after such acquisition, merger, consolidation or other reorganization is owned by persons who in the aggregate owned less than 20% of the Company’s combined voting power represented by the Company’s outstanding securities immediately prior to such acquisition, merger, consolidation or other reorganization;

(ii) A sale of more than fifty percent (50%) of the outstanding shares of each class of capital stock of the Company to a person, entity or group other than a person, entity or group affiliated with the Company; or

(iii) The sale, transfer or other disposition of all or substantially all of the Company’s assets to a person, entity or group other than a person, entity or group affiliated with the Company.

A transaction shall not constitute a Change in Control if: (i) its principal purpose is to change the state of the Company’s incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transactions; or (ii) it is an equity financing primarily for capital raising purposes. In addition, an IPO shall not constitute a Change in Control. If the timing of payments provided under an Award Agreement is based on or triggered by a Change in Control then, to extent necessary to avoid violating Code Section 409A, a Change in Control must also constitute a Change in Control Event.

(k) **“Change in Control Event”** has the meaning provided to such term under Code Section 409A and the applicable regulations and guidance promulgated thereunder.

(l) **“Charter”** means the Company’s Amended and Restated Certificate of Incorporation, as amended as may be amended from time to time.

(m) **“Code”** means the Internal Revenue Code of 1986, as amended, and the regulations and interpretations promulgated thereunder.

(n) **“Committee”** means a committee consisting of members of the Board that is appointed by the Board (as described in Section 3) to administer the Plan. If no Committee has been appointed, the full Board shall constitute the Committee.

(o) **“Common Stock”** means the Company’s common stock (as defined in the Charter and with the rights and obligations provided under the Charter) and any other securities into which such shares are changed, for which such shares are exchanged or which may be issued in respect thereof.

(p) **“Company”** means Greenwich Life Sciences, Inc., a Delaware corporation.

(q) **“Consultant”** means an individual (or entity) which performs bona fide services to the Company, a Parent, a Subsidiary or an Affiliate other than as an Employee or Non-Employee Director.

(r) “**Disability**” means the following with respect to a Participant:

- i. For all ISOs, the permanent and total disability of the Participant within the meaning of Section 22(e)(3) of the Code;
- ii. For all Awards which are considered nonqualified deferred compensation under Code Section 409A and for which payment can be made on account of the Participant’s disability, the disability of the Participant within the meaning of Section 409A of the Code; or
- iii. For all other Awards, the Participant’s medically determinable physical or mental incapacitation such that for a continuous period of not less than twelve (12) months, the Participant is unable to engage in any substantial gainful activity or which can be expected to result in death.

Any question as to the existence of the Participant’s physical or mental incapacitation as to which the Participant or Participant’s representative and the Company cannot agree shall be determined in writing by a qualified independent physician selected by the Company. The physician’s determination of Disability shall be made in writing to the Company and the determination shall be final and conclusive for all purposes of the Participant’s Awards.

(s) “**Employee**” means any individual who is a common-law employee of the Company, or of a Parent, or of a Subsidiary or of an Affiliate.

(t) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

(u) “**Exercise Price**” means, in the case of an Option, the amount for which a Share may be purchased upon exercise of such Option, as specified in the applicable Stock Option Agreement. “Exercise Price,” in the case of a SAR, means an amount, as specified in the applicable SAR Agreement, which is subtracted from the Fair Market Value in determining the amount payable to a Participant upon exercise of such SAR.

(v) “**Fair Market Value**” means the market price of a Share, determined by the Committee as follows:

(i) If the Shares were traded on a stock exchange (such as the New York Stock Exchange, NYSE Amex, the NASDAQ Global Market or NASDAQ Capital Market) at the time of determination, then the Fair Market Value shall be equal to the regular session closing price for such stock as reported by such exchange (or the exchange or market with the greatest volume of trading in the Shares) on the date of determination, or if there were no sales on such date, on the last date preceding such date on which a closing price was reported;

(ii) If the Shares were traded on the OTC Markets at the time of determination, then the Fair Market Value shall be equal to the last-sale price reported by the OTC Markets for such date, or if there were no sales on such date, on the last date preceding such date on which a sale was reported; and

(iii) If neither of the foregoing provisions is applicable, then the Fair Market Value shall be determined by the Committee in good faith using a reasonable application of a reasonable valuation method as the Committee deems appropriate.

Whenever possible, the determination of Fair Market Value by the Committee shall be based on the prices reported by the applicable exchange or the OTC Markets, as applicable, or a nationally recognized publisher of stock prices or quotations (including an electronic on-line publication). Such determination shall be conclusive and binding on all persons.

(w) “**Incentive Stock Option**” or “**ISO**” means an incentive stock option described in Code section 422.

(x) “**IPO**” means an initial public offering by the Company of its equity securities pursuant to an effective registration statement filed with the SEC.

(y) “**Key Employee**” means an Employee, Non-Employee Director or Consultant who has been selected by the Committee to receive an Award under the Plan.

(z) “**Net Exercise**” means, to the extent that a Stock Option Agreement so provides and as permitted by applicable law, an arrangement pursuant to which the number of Shares issued to the Optionee in connection with the Optionee’s exercise of the Option will be reduced by the Company’s retention of a portion of such Shares. Upon such a net exercise of an Option, the Optionee will receive a net number of Shares that is equal to (i) the number of Shares as to which the Option is being exercised minus (ii) the quotient (rounded down to the nearest whole number) of the aggregate Exercise Price of the Shares being exercised divided by the Fair Market Value of a Share on the Option exercise date. The number of Shares covered by clause (ii) will be retained by the Company and not delivered to the Optionee. No fractional Shares will be created as a result of a Net Exercise and the Optionee must contemporaneously pay for any portion of the aggregate Exercise Price that is not covered by the Shares retained by the Company under clause (ii). The number of Shares delivered to the Optionee may be further reduced if Net Exercise is utilized under Section 14(b) to satisfy applicable tax withholding obligations.

(aa) “**Non-Employee Director**” means a member of the Board who is not an Employee.

(bb) “**Nonstatutory Stock Option**” or “**NSO**” means a stock option that is not an ISO.

(cc) “**Officer**” means an individual who is an officer of the Company within the meaning of Rule 16a-1(f) of the Exchange Act.

(dd) “**Option**” means an ISO or NSO granted under the Plan entitling the Optionee to purchase Shares under the Plan as provided in Section 6.

(ee) “**Optionee**” means an individual, estate or other entity that holds an Option.

(ff) **"Other Equity Award"** means an award (other than an Option, SAR, Stock Unit, Restricted Stock Grant or Cash Award) which derives its value from the value of Shares and/or from increases in the value of Shares. Settlement of Other Equity Awards may be in the form of Shares and/or cash as determined by the Committee.

(gg) **"Parent"** means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the Adoption Date shall be considered a Parent commencing as of such date.

(hh) **"Participant"** means an individual or estate or other entity that holds an Award.

(ii) **"Plan"** means this Greenwich Life Sciences, Inc. 2019 Equity Incentive Plan as it may be amended from time to time.

(jj) **"Re-Load Option"** means a new Option or SAR that is automatically granted to a Participant as result of such Participant's exercise of an Option or SAR.

(kk) **"Re-Price"** means that the Company has lowered or reduced the Exercise Price of outstanding Options and/or outstanding SARs and/or outstanding Other Equity Awards for any Participant(s) in a manner described by SEC Regulation S-K Item 402(d)(2)(viii) (or as described in any successor provision(s) or definition(s)). For avoidance of doubt, Re-Price also includes any exchange of Options or SARs for other Awards or cash.

(ll) **"Restricted Stock Grant"** means Shares awarded under the Plan as provided in Section 9.

(mm) **"Restricted Stock Grant Agreement"** means the agreement described in Section 9 evidencing each Award of a Restricted Stock Grant.

(nn) **"Rule 16b-3"** means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(oo) **"SAR Agreement"** means the agreement described in Section 8 evidencing each Award of a Stock Appreciation Right.

(pp) **"SEC"** means the Securities and Exchange Commission.

(qq) **"Section 16 Persons"** means those Officers or directors or Non-Employee Directors or other persons who are subject to Section 16 of the Exchange Act.

(rr) **"Securities Act"** means the Securities Act of 1933, as amended.

(ss) **"Separation From Service"** means a Participant's separation from service with the Company within the meaning of Code Section 409A.

(tt) “**Service**” means service as an Employee, Non-Employee Director or Consultant. Service will be deemed terminated as soon as the entity to which Service is being provided is no longer either (i) the Company, (ii) a Parent, (iii) a Subsidiary or (iv) an Affiliate. The Committee determines when Service commences and when Service terminates. The Committee may determine whether any Company transaction, such as a sale or spin-off of a division or subsidiary that employs a Participant, shall be deemed to result in termination of Service for purposes of any affected Awards, and the Committee’s decision shall be final, conclusive and binding.

(uu) “**Share**” means one share of Common Stock.

(vv) “**Stock Appreciation Right or SAR**” means a stock appreciation right awarded under the Plan as provided in Section 8.

(ww) “**Stock Option Agreement**” means the agreement described in Section 6 evidencing each Award of an Option.

(xx) “**Stock Unit**” means a bookkeeping entry representing the equivalent of one Share awarded under the Plan as provided in Section 10.

(yy) “**Stock Unit Agreement**” means the agreement described in Section 10 evidencing each Award of Stock Units.

(zz) “**Stockholder Approval Date**” means the date that the Company’s stockholders approve this Plan.

(aaa) “**Stockholders Agreement**” means any applicable agreement between the Company’s stockholders and/or investors that provides certain rights and obligations for stockholders.

(bbb) “**Subsidiary**” means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Subsidiary on a date after the Adoption Date shall be considered a Subsidiary commencing as of such date.

(ccc) “**Termination Date**” means the date on which a Participant’s Service terminates as determined by the Committee.

(ddd) “**10-Percent Shareholder**” means an individual who owns more than ten percent (10%) of the total combined voting power of all classes of outstanding stock of the Company, its Parent or any of its Subsidiaries. In determining stock ownership, the attribution rules of section 424(d) of the Code shall be applied.

SECTION 3. ADMINISTRATION.

(a) **Committee Composition.** A Committee appointed by the Board shall administer the Plan. The Board shall designate one of the members of the Committee as chairperson. Members of the Committee shall serve for such period of time as the Board may determine and shall be subject to removal by the Board at any time. The Board may also at any time terminate the functions of the Committee and reassume all powers and authority previously delegated to the Committee.

Effective with the Shares being publicly traded or the Company being subject to the reporting requirements of the Exchange Act, with respect to Awards to Section 16 Persons, the Committee shall consist either (i) solely of two or more individuals who satisfy the requirements of Rule 16b-3 (or its successor) under the Exchange Act or (ii) of the full Board. The Board may also appoint one or more separate committees of the Board, each composed of directors of the Company who need not qualify under Rule 16b-3, who may administer the Plan with respect to Key Employees who are not Section 16 Persons, may grant Awards under the Plan to such Key Employees and may determine all terms of such Awards. To the extent permitted by applicable law, the Board may also appoint a committee, composed of one or more Officers of the Company, that may authorize Awards to Employees (who are not Section 16 Persons) within parameters specified by the Board and consistent with any limitations imposed by applicable law.

(b) **Authority of the Committee.** Subject to the provisions of the Plan, the Committee shall have full authority and discretion to take any actions it deems necessary or advisable for the administration of the Plan. Such actions shall include without limitation:

- (i) selecting Key Employees who are to receive Awards under the Plan;
- (ii) determining the type, number, vesting requirements, performance conditions (if any) and their degree of satisfaction, and other features and conditions of such Awards and amending such Awards;
- (iii) correcting any defect, supplying any omission, or reconciling or clarifying any inconsistency in the Plan or any Award Agreement;
- (iv) accelerating the vesting, or extending the post-termination exercise term, or waiving restrictions, of Awards at any time and under such terms and conditions as it deems appropriate;
- (v) interpreting the Plan and any Award Agreements;
- (vi) making all other decisions relating to the operation of the Plan; and

(vii) granting Awards to Key Employees who are foreign nationals on such terms and conditions different from those specified in the Plan, which may be necessary or desirable to foster and promote achievement of the purposes of the Plan, and adopting such modifications, procedures, and/or subplans (with any such subplans attached as appendices to the Plan) and the like as may be necessary or desirable to comply with provisions of the laws or regulations of other countries or jurisdictions to ensure the viability of the benefits from Awards granted to Participants employed in such countries or jurisdictions, or to meet the requirements that permit the Plan to operate in a qualified or tax efficient manner, and/or comply with applicable foreign laws or regulations.

The Committee may adopt such rules or guidelines, as it deems appropriate to implement the Plan. The Committee's determinations under the Plan shall be final, conclusive and binding on all persons. The Committee's decisions and determinations need not be uniform and may be made selectively among Participants in the Committee's sole discretion. The Committee's decisions and determinations will be afforded the maximum deference provided by applicable law.

(c) **Indemnification.** To the maximum extent permitted by applicable law, each member of the Committee, or of the Board, or any persons (including without limitation Employees and Officers) who are delegated by the Board or Committee to perform administrative functions in connection with the Plan, shall be indemnified and held harmless by the Company against and from (i) any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by him or her in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action taken or failure to act under the Plan or any Award Agreement, and (ii) from any and all amounts paid by him or her in settlement thereof, with the Company's approval, or paid by him or her in satisfaction of any judgment in any such claim, action, suit, or proceeding against him or her, provided he or she shall give the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled under the Company's Bylaws or Charter, by contract, as a matter of law, or otherwise, or under any power that the Company may have to indemnify them or hold them harmless.

SECTION 4. GENERAL.

(a) **Eligibility.** Only Employees, Non-Employee Directors and Consultants shall be eligible for designation as Key Employees by the Committee.

(b) **Incentive Stock Options.** Only Key Employees who are common-law employees of the Company, a Parent or a Subsidiary shall be eligible for the grant of ISOs. In addition, a Key Employee who is a 10-Percent Shareholder shall not be eligible for the grant of an ISO unless the requirements set forth in section 422(c)(5) of the Code are satisfied. If and to the extent that any Shares are issued under a portion of any Option that exceeds the \$100,000 limitation of Section 422 of the Code, such Shares shall not be treated as issued under an ISO notwithstanding any designation otherwise. Certain decisions, amendments, interpretations and actions by the Committee and certain actions by a Participant may cause an Option to cease to qualify as an ISO pursuant to the Code and by accepting an Option the Participant agrees in advance to such disqualifying action taken by either the Participant, the Committee or the Company.

(c) **Restrictions on Shares.** Any Shares issued pursuant to an Award shall be subject to such Company policies, rights of repurchase, rights of first refusal and other transfer restrictions as the Committee may determine. Such restrictions shall apply in addition to any restrictions that may apply to holders of Shares generally and shall also comply to the extent necessary with applicable law. In no event shall the Company be required to issue fractional Shares under this Plan. Subject to the following sentence and only to the extent applicable, no Option may be exercised by a Participant and no Shares will be issued to a Participant to the extent such exercise or issuance of Shares would cause the termination of the Company's status as a "S corporation" under the Code. The requirements of the preceding sentence will not be applicable on or after the earlier of the date of a Change in Control or the date when the Company is not (or no longer is) a S corporation.

(d) **Beneficiaries.** A Participant may designate one or more beneficiaries with respect to an Award by timely filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Participant's death. If no beneficiary was designated or if no designated beneficiary survives the Participant, then after a Participant's death any vested Award(s) shall be transferred or distributed to the Participant's estate.

(e) **Performance Conditions.** The Committee may, in its discretion, include performance conditions in any Award.

(f) **Stockholder Rights.** A Participant, or a transferee of a Participant, shall have no rights as a stockholder (including without limitation voting rights or dividend or distribution rights) with respect to any Common Stock covered by an Award until such person becomes entitled to receive such Common Stock, has satisfied any applicable withholding or tax obligations relating to the Award and the Common Stock has been issued to the Participant. No adjustment shall be made for cash or stock dividends or other rights for which the record date is prior to the date when such Common Stock is issued, except as expressly provided in Section 11. The issuance of an Award may be subject to and conditioned upon the Participant's agreement to become a party to a Stockholders Agreement and be bound by its terms.

(g) **Buyout of Awards.** The Committee may at any time offer to buy out, for a payment in cash or cash equivalents (including without limitation Shares issued at Fair Market Value that may or may not be issued under this Plan), an Award previously granted based upon such terms and conditions as the Committee shall establish.

(h) **Termination of Service.** Unless the applicable Award Agreement or employment agreement provides otherwise (and in such case, the Award Agreement or employment agreement shall govern as to the consequences of a termination of Service for such Awards subject to Section 4(i)), the following rules shall govern the vesting, exercisability and term of outstanding Awards held by a Participant in the event of termination of such Participant's Service (in all cases subject to the term of the Option or SAR or Other Equity Award as applicable):

(i) if the Service of a Participant is terminated for Cause, then all Options, Cash Awards, Other Equity Awards, SARs, unvested portions of Stock Units and unvested portions of Restricted Stock Grants shall terminate and be forfeited immediately without consideration as of the Termination Date (except for repayment of any amounts the Participant had paid to the Company to acquire unvested Shares underlying the forfeited Awards);

(ii) if the Service of Participant is terminated due to the Participant's death or Disability, then the vested portion of his/her then-outstanding Options/SARs/Other Equity Awards may be exercised by such Participant or his or her personal representative within six months after the Termination Date and all unvested portions of any outstanding Awards shall be forfeited without consideration as of the Termination Date (except for repayment of any amounts the Participant had paid to the Company to acquire unvested Shares underlying the forfeited Awards); and

(iii) if the Service of Participant is terminated for any reason other than for Cause or other than due to death or Disability, then the vested portion of his/her then-outstanding Options/SARs/Other Equity Awards may be exercised by such Participant within three months after the Termination Date and all unvested portions of any outstanding Awards shall be forfeited without consideration as of the Termination Date (except for repayment of any amounts the Participant had paid to the Company to acquire unvested Shares underlying the forfeited Awards).

(i) **California Participants.** Awards to California Participants shall also be subject to the following terms regarding the time period to exercise vested Options or SARs after termination of Service. These additional terms shall apply until such time that the Shares are publicly traded and/or the Company is subject to the reporting requirements of the Exchange Act: In the event of termination of a Participant's Service, (i) if such termination was for reasons other than death or Disability or Cause, the Participant shall have at least 30 days after the date of such termination to exercise any of his/her vested outstanding Options or SARs (but in no event later than the expiration of the term of such Options or SARs established by the Committee as of the Award date) or (ii) if such termination was due to death or Disability, the Participant shall have at least six months after the date of such termination to exercise any of his/her vested outstanding Options or SARs (but in no event later than the expiration of the term of such Options or SARs established by the Committee as of the Award date).

(j) **Intentionally Omitted.**

(k) **Suspension or Termination of Awards.** To the extent provided in an Award Agreement, if at any time (including after a notice of exercise has been delivered) the Committee (or the Board), reasonably believes that a Participant has committed an act of Cause (which includes a failure to act), the Committee (or Board) may suspend the Participant's right to exercise any Option or SAR (or vesting of Restricted Stock Grants or Stock Units) pending a determination of whether there was in fact an act of Cause. To the extent provided in an Award Agreement, if the Committee (or the Board) determines a Participant has committed an act of Cause, neither the Participant nor his or her estate shall be entitled to exercise the outstanding Option or SAR whatsoever and the Participant's outstanding Awards shall then terminate without consideration. Any determination by the Committee (or the Board) with respect to the foregoing shall be final, conclusive and binding on all interested parties.

(l) **Code Section 409A.** Notwithstanding anything in the Plan to the contrary, the Plan and Awards granted hereunder are intended to comply with the requirements of Code Section 409A and shall be interpreted in a manner consistent with such intention. In the event that any provision of the Plan or an Award Agreement is determined by the Committee to not comply with the applicable requirements of Code Section 409A or the Treasury Regulations or other guidance issued thereunder, the Committee shall have the authority to take such actions and to make such changes to the Plan or an Award Agreement as the Committee deems necessary to comply with such requirements (including without limitation, after the grant date of an Award, increasing the Exercise Price to equal what was the Fair Market Value on the grant date of the Award). Each payment to a Participant made pursuant to this Plan shall be considered a separate payment and not one of a series of payments for purposes of Code Section 409A. Notwithstanding the foregoing or anything elsewhere in the Plan or an Award Agreement to the contrary, if upon a Participant's Separation From Service he/she is then a "specified employee" (as defined in Code Section 409A), then solely to the extent necessary to comply with Code Section 409A and avoid the imposition of taxes under Code Section 409A, the Company shall defer payment of "nonqualified deferred compensation" subject to Code Section 409A payable as a result of and within six (6) months following such Separation From Service under this Plan until the earlier of (i) the first (1st) business day of the seventh (7th) month following the Participant's Separation From Service, or (ii) ten (10) days after the Company receives written confirmation of the Participant's death. Any such delayed payments shall be made without interest. While it is intended that all payments and benefits provided under this Plan will be exempt from or comply with Code Section 409A, the Company makes no representation or covenant to ensure that the Awards and payments under this Plan are exempt from or compliant with Code Section 409A. The Company will have no liability to any Participant or any other party if a payment or benefit under this Plan or any Award is challenged by any taxing authority or is ultimately determined not to be exempt or compliant. Each Participant further understands and agrees that each Participant will be entirely responsible for any and all taxes on any benefits payable to the Participant as a result of this Plan or any Award. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on a Participant by Code Section 409A or for any damages for failing to comply with Code Section 409A.

(m) **Electronic Communications.** Subject to compliance with applicable law and/or regulations, an Award Agreement or other documentation or notices relating to the Plan and/or Awards may be communicated to Participants by electronic media.

(n) **Unfunded Plan.** Insofar as it provides for Awards, the Plan shall be unfunded. Although bookkeeping accounts may be established with respect to Participants who are granted Awards under this Plan, any such accounts will be used merely as a bookkeeping convenience. The Company shall not be required to segregate any assets which may at any time be represented by Awards, nor shall this Plan be construed as providing for such segregation, nor shall the Company or the Committee be deemed to be a trustee of stock or cash to be awarded under the Plan.

(o) **Liability of Company Plan.** The Company (or members of the Board or Committee) shall not be liable to a Participant or other persons as to: (i) the non-issuance or sale of Shares as to which the Company has been unable to obtain from any regulatory body having jurisdiction the authority deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder; and (ii) any unexpected or adverse tax consequence or any tax consequence expected, but not realized, by any Participant or other person due to the grant, receipt, exercise or settlement of any Award granted under this Plan.

(p) **Reformation.** In the event any provision of this Plan shall be held illegal or invalid for any reason, such provisions will be reformed by the Board if possible and to the extent needed in order to be held legal and valid. If it is not possible to reform the illegal or invalid provisions then the illegality or invalidity shall not affect the remaining parts of this Plan, and this Plan shall be construed and enforced as if the illegal or invalid provision had not been included.

(q) **Successor Provision.** Any reference to a statute, rule or regulation, or to a section of a statute, rule or regulation, is a reference to that statute, rule, regulation, or section as amended from time to time, both before and after the Adoption Date and including any successor provisions.

(r) **Governing Law.** This Plan, and (unless otherwise provided in the Award Agreement) all Awards, shall be construed in accordance with and governed by the laws of the State of Delaware, but without regard to its conflict of law provisions. The Committee may provide that any dispute as to any Award shall be presented and determined in such forum as the Committee may specify, including through binding arbitration. Unless otherwise provided in the Award Agreement, recipients of an Award under the Plan are deemed to submit to the exclusive jurisdiction and venue of the federal or state courts of Delaware to resolve any and all issues that may arise out of or relate to the Plan or any related Award Agreement.

(s) **No Re-Pricing of Options or SARs or Other Equity Awards or Award of Re-Load Options.**

Notwithstanding anything to the contrary, (i) outstanding Options or SARs or Other Equity Awards may not be Re-Priced and (ii) Re-Load Options may not be awarded, in each case without the approval of Company stockholders. Moreover, any amendment to the Plan or any Award Agreement that results in the Re-Pricing of an Option or SAR or Other Equity Award issued under the Plan shall not be effective without prior approval of the stockholders of the Company. For this purpose, repricing includes a reduction in the Exercise Price of an Option or a SAR or the cancellation of an Option or SAR in exchange for cash, Options or SARs or Other Equity Award with an Exercise Price less than the Exercise Price of the cancelled Option or SAR, other Awards under the Plan or any other consideration provided by the Company.

(t) **Other Awards.** The Committee may in its discretion issue Other Equity Awards and/or Cash Awards to Key Employees. The terms and conditions of any such Awards shall be evidenced by an Award Agreement between the Participant and the Company.

(u) **Intentionally Omitted.**

(v) **Deferral Elections.** The Committee may permit a Participant to elect to defer his or her receipt of the payment of cash or the delivery of Shares that would otherwise be due to such Participant by virtue of the exercise, earn out or vesting of an Award made under the Plan. If any such election is permitted, the Committee shall establish rules and procedures for such payment deferrals, including the possible (a) payment or crediting of reasonable interest on such deferred amounts credited in cash, and (b) the payment or crediting of dividend equivalents in respect of deferrals credited in units of Common Stock. The Company and the Committee shall not be responsible to any person in the event that the payment deferral does not result in deferral of income for tax purposes.

(w) **Payment of Non-Employee Director Cash Fees with Equity Awards.** If the Board affirmatively decides to authorize such a process, each Non-Employee Director may elect to receive a Restricted Stock Grant (or Stock Units or Other Equity Awards) issued under the Plan in lieu of payment of all or a portion of his or her annual cash retainer and/or any other cash fees including without limitation meeting fees, committee service fees and participation fees. Any such elections made by a Non-Employee Director shall be effected no later than the time permitted by applicable law and in accordance with the Company's insider trading policies and/or other policies. The aggregate grant date fair market value of any Restricted Stock Grants or Stock Units or Other Equity Awards issued pursuant to this Section 4(v) is intended to be equivalent to the value of the foregone cash fees. Any cash fees not elected to be received as a Restricted Stock Grant or Stock Units or Other Equity Awards shall be payable in cash in accordance with the Company's standard payment procedures. The Board in its discretion shall determine the terms, conditions and procedures for implementing this Section 4(v) and may also modify or terminate its operation at any time.

SECTION 5. SHARES SUBJECT TO PLAN AND SHARE LIMITS.

Basic Limitations. The Common Stock issuable under the Plan shall be authorized but unissued Shares or treasury Shares. Subject to adjustment as provided in Section 11, the maximum aggregate number of Shares that may be issued:

(i) under the Plan shall not exceed 4,000,000 Shares (the "Share Limit"); and

(ii) pursuant to the exercise of ISOs granted under this Plan shall not exceed 4,000,000 Shares (the "ISO Limit").

(a) **Share Accounting.** This Section 5(b) describes the Share accounting process for Awards issued under the Plan with respect to the Share Limit and ISO Limit.

(i) There shall be counted against the numerical limitations in Section 5(a) the gross number of Shares subject to issuance upon exercise or used for determining payment or settlement of Awards. The below clauses (ii), (iii), (iv), (v) and (vi) of this Section 5(b) seek to clarify the intent of the foregoing sentence. The Shares issued (or settled) under an Award will be counted against the Share Limit (and ISO Limit if the Award is an ISO) at the time(s) of exercise or settlement of the Award. For avoidance of doubt, Shares that are withheld as payment for the Award's Exercise Price or applicable withholding taxes shall be counted against the Share Limit (and ISO Limit if the Award is an ISO).

(ii) For avoidance of doubt, each Share issued (or settled or exercised) under any Award shall be counted against the Share Limit as one Share.

(iii) For avoidance of doubt, whether or not a SAR is settled with any Shares, the gross number of Shares subject to the exercise and which are used for determining the benefit payable under such SAR shall be counted against the Share Limit, regardless of the number of Shares actually used to settle the SAR upon such exercise.

(iv) For avoidance of doubt, to the extent an Option is exercised via a Cashless Exercise or Net Exercise or is not otherwise fully settled with Shares, then the gross number of Shares subject to the exercise and which are used for determining the benefit payable under such Option shall be counted against the Share Limit (and shall also count against the ISO Limit if the Option being exercised is an ISO), regardless of the number of Shares actually issued to the Participant upon such exercise.

(v) If any portion of an Award is forfeited, terminated without consideration, or expires unexercised, (collectively, "Forfeited Shares"), the gross number of such Forfeited Shares shall again be available for Awards under the Plan and shall not be counted against the Share Limit or ISO Limit.

(v) For avoidance of doubt, if any Awards are settled or paid in cash in lieu of stock and/or are exchanged for other Awards (collectively, "Settled Shares"), the gross number of such Settled Shares shall be counted against the Share Limit (and ISO Limit if the Award is an ISO).

(b) **Substitute Awards.** Any Substitute Awards including without limitation any Shares that are delivered and any Awards that are granted by, or become obligations of, the Company, as a result of the assumption by the Company of, or in substitution for, outstanding awards previously granted by another entity (as provided below) shall not be counted toward the Share Limit or ISO Limit. Substitute Awards shall not count toward the Share Limit, nor shall Shares subject to a Substitute Award again be available for Awards under the Plan as provided in Section 5(b) above. Additionally, in the event that a company acquired by the Company or any Parent or any Subsidiary or any Affiliate or with which the Company or any Parent or any Subsidiary or any Affiliate combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not count toward the Share Limit; provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not Employees or Board members prior to such acquisition or combination.

(c) **Dividend Equivalents.** Any dividend equivalents distributed under the Plan in the form of Shares shall be counted against the Share Limit (with each Share that is distributed counting as one Share against the Share Limit). Dividend equivalents will not be paid (or accrue) on unexercised Options or unexercised SARs.

SECTION 6. TERMS AND CONDITIONS OF OPTIONS.

(a) **Stock Option Agreement.** Each Award of an Option under the Plan shall be evidenced by a Stock Option Agreement between the Optionee and the Company. Such Option shall be subject to all applicable terms and conditions of the Plan and may be subject to any other terms and conditions that are not inconsistent with the Plan (including without limitation any performance conditions). The provisions of the various Stock Option Agreements entered into under the Plan need not be identical. The Stock Option Agreement shall also specify whether the Option is an ISO and if not specified then the Option shall be an NSO.

(b) **Number of Shares.** Each Stock Option Agreement shall specify the number of Shares that are subject to the Option and shall provide for the adjustment of such number in accordance with Section 11.

(c) **Exercise Price.** An Option's Exercise Price shall be established by the Committee and set forth in a Stock Option Agreement. Except with respect to (i) outstanding stock options being assumed or (ii) Options being granted in exchange for cancellation of options granted by another issuer as provided under Section 6(e) or (iii) an NSO granted with a per share Exercise Price that is less than the per Share Fair Market Value on the date of Award and further provided that the Committee expressly acknowledges in its granting resolutions its awareness that such Option may be subject to the requirements of Code Section 409A, the Exercise Price of an Option shall not be less than 100% of the Fair Market Value (110% for 10-Percent Shareholders in the case of ISOs) of a Share on the date of Award.

(d) **Exercisability and Term.** Each Stock Option Agreement shall specify the date when all or any installment of the Option is to become vested and/or exercisable. The Stock Option Agreement shall also specify the term of the Option; provided, however that the term of an Option shall in no event exceed ten (10) years from the date of Award. An ISO that is granted to a 10-Percent Shareholder shall have a maximum term of five (5) years. No Option can be exercised after the expiration date specified in the applicable Stock Option Agreement. A Stock Option Agreement may provide for accelerated exercisability in the event of the Optionee's death, Disability or retirement or other events. A Stock Option Agreement may permit an Optionee to exercise an Option before it is vested (an "early exercise"), subject to the Company's right of repurchase at the original Exercise Price of any Shares acquired under the unvested portion of the Option which right of repurchase shall lapse at the same rate the Option would have vested had there been no early exercise. In no event shall the Company be required to issue fractional Shares upon the exercise of an Option and the Committee may specify a minimum number of Shares that must be purchased in any one Option exercise.

(e) **Modifications or Assumption of Options.** Within the limitations of the Plan, the Committee may modify, extend or assume outstanding Options or may accept the cancellation of outstanding stock options (whether granted by the Company or by another issuer) in return for the grant of new Options for the same or a different number of Shares and at the same or a different Exercise Price. No modification of an Option shall, without the consent of the Optionee, impair his or her rights or increase his or her obligations under such Option.

(f) **Assignment or Transfer of Options.** Except as otherwise provided in the applicable Stock Option Agreement and then only to the extent permitted by applicable law, no Option shall be transferable by the Optionee other than by will or by the laws of descent and distribution. Except as otherwise provided in the applicable Stock Option Agreement, an Option may be exercised during the lifetime of the Optionee only by Optionee or by the guardian or legal representative of the Optionee. Except as otherwise provided in the applicable Stock Option Agreement, no Option or interest therein may be subject to a short position nor may any Option or interest therein be gifted, transferred, assigned, alienated, pledged, hypothecated, attached, sold, or encumbered by the Optionee during his/her lifetime, whether by operation of law or otherwise, or be made subject to execution, attachment or similar process.

SECTION 7. PAYMENT FOR OPTION SHARES.

(a) **General Rule.** The entire Exercise Price of Shares issued upon exercise of Options shall be payable in cash (or check) at the time when such Shares are purchased by the Optionee, except as follows and if so provided for in an applicable Stock Option Agreement:

(i) In the case of an ISO granted under the Plan, payment shall be made only pursuant to the express provisions of the applicable Stock Option Agreement. The Stock Option Agreement may specify that payment may be made in any form(s) described in this Section 7.

(ii) In the case of an NSO granted under the Plan, the Committee may in its discretion, at any time accept payment in any form(s) described in this Section 7.

(b) **Surrender of Stock.** To the extent that the Committee makes this Section 7(b) applicable to an Option in a Stock Option Agreement, payment for all or any part of the Exercise Price may be made with Shares which have already been owned by the Optionee for such duration as shall be specified by the Committee. Such Shares shall be valued at their Fair Market Value on the date when the new Shares are purchased under the Plan.

(c) **Cashless Exercise.** To the extent that the Committee makes this Section 7(c) applicable to an Option in a Stock Option Agreement, payment for all or a part of the Exercise Price may be made through Cashless Exercise.

(d) **Net Exercise.** To the extent that the Committee makes this Section 7(d) applicable to an Option in a Stock Option Agreement, payment for all or a part of the Exercise Price may be made through Net Exercise.

(e) **Other Forms of Payment.** To the extent that the Committee makes this Section 7(e) applicable to an Option in a Stock Option Agreement, payment may be made in any other form that is consistent with applicable laws, regulations and rules and approved by the Committee.

SECTION 8. TERMS AND CONDITIONS OF STOCK APPRECIATION RIGHTS.

(a) **SAR Agreement.** Each Award of a SAR under the Plan shall be evidenced by a SAR Agreement between the Participant and the Company. Such SAR shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan (including without limitation any performance conditions). A SAR Agreement may provide for a maximum limit on the amount of any payout notwithstanding the Fair Market Value on the date of exercise of the SAR. The provisions of the various SAR Agreements entered into under the Plan need not be identical. SARs may be granted in consideration of a reduction in the Participant's other compensation.

(b) **Number of Shares.** Each SAR Agreement shall specify the number of Shares to which the SAR pertains and is subject to adjustment of such number in accordance with Section 11.

(c) **Exercise Price.** Each SAR Agreement shall specify the Exercise Price. A SAR Agreement may specify an Exercise Price that varies in accordance with a predetermined formula while the SAR is outstanding. Except with respect to outstanding stock appreciation rights being assumed or SARs being granted in exchange for cancellation of stock appreciation rights granted by another issuer as provided under Section 8(f), the Exercise Price of a SAR shall not be less than 100% of the Fair Market Value on the date of Award.

(d) **Exercisability and Term.** Each SAR Agreement shall specify the date when all or any installment of the SAR is to become exercisable. The SAR Agreement shall also specify the term of the SAR which shall not exceed ten (10) years from the date of Award. No SAR can be exercised after the expiration date specified in the applicable SAR Agreement. A SAR Agreement may provide for accelerated exercisability in the event of the Participant's death, or Disability or other events. SARs may be awarded in combination with Options or other Awards, and such an Award may provide that the SARs will not be exercisable unless the related Options or other Awards are forfeited. A SAR may be included in an ISO only at the time of Award but may be included in an NSO at the time of Award or at any subsequent time, but not later than six (6) months before the expiration of such NSO. A SAR granted under the Plan may provide that it will be exercisable only in the event of a Change in Control.

(e) **Exercise of SARs.** If, on the date when a SAR expires, the Exercise Price under such SAR is less than the Fair Market Value on such date but any portion of such SAR has not been exercised or surrendered, then such SAR may automatically be deemed to be exercised as of such date with respect to such portion to the extent so provided in the applicable SAR agreement. Upon exercise of a SAR, the Participant (or any person having the right to exercise the SAR after Participant's death) shall receive from the Company (i) Shares, (ii) cash or (iii) any combination of Shares and cash, as the Committee shall determine. The amount of cash and/or the Fair Market Value of Shares received upon exercise of SARs shall, in the aggregate, be equal to the amount by which the Fair Market Value (on the date of surrender) of the Shares subject to the SARs exceeds the Exercise Price of the Shares.

(f) **Modification or Assumption of SARs.** Within the limitations of the Plan, the Committee may modify, extend or assume outstanding SARs or may accept the cancellation of outstanding SARs (including stock appreciation rights granted by another issuer) in return for the grant of new SARs for the same or a different number of Shares and at the same or a different Exercise Price. No modification of a SAR shall, without the consent of the Participant, impair his or her rights or increase his or her obligations under such SAR.

(g) **Assignment or Transfer of SARs.** Except as otherwise provided in the applicable SAR Agreement and then only to the extent permitted by applicable law, no SAR shall be transferable by the Participant other than by will or by the laws of descent and distribution. Except as otherwise provided in the applicable SAR Agreement, a SAR may be exercised during the lifetime of the Participant only by the Participant or by the guardian or legal representative of the Participant. No SAR or interest therein may be transferred, assigned, alienated, pledged, hypothecated, attached, sold, or encumbered by the Participant during his or her lifetime, whether by operation of law or otherwise, or be made subject to execution, attachment or similar process.

SECTION 9. TERMS AND CONDITIONS FOR RESTRICTED STOCK GRANTS.

(a) **Restricted Stock Grant Agreement.** Each Restricted Stock Grant awarded under the Plan shall be evidenced by a Restricted Stock Grant Agreement between the Participant and the Company. Each Restricted Stock Grant shall be subject to all applicable terms and conditions of the Plan and may be subject to any other terms and conditions that are not inconsistent with the Plan (including without limitation any performance conditions). The provisions of the Restricted Stock Grant Agreements entered into under the Plan need not be identical.

(b) **Number of Shares and Payment.** Each Restricted Stock Grant Agreement shall specify the number of Shares to which the Restricted Stock Grant pertains and is subject to adjustment of such number in accordance with Section 11. Restricted Stock Grants may be issued with or without cash consideration under the Plan.

(c) **Vesting Conditions.** Each Restricted Stock Grant may or may not be subject to vesting. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the Restricted Stock Grant Agreement. A Restricted Stock Grant Agreement may provide for accelerated vesting in the event of the Participant's death, or Disability or other events.

(d) **Voting and Dividend Rights.** The holder of a Restricted Stock Grant (irrespective of whether the Shares subject to the Restricted Stock Grant are vested or unvested) awarded under the Plan shall have the same voting, dividend and other rights as other holders of Common Stock. However, any dividends received on Shares that are unvested (whether such dividends are in the form of cash or Shares) may be subject to the same vesting conditions and restrictions as the Restricted Stock Grant with respect to which the dividends were paid. Such additional Shares issued as dividends that are subject to the Restricted Stock Grant shall not reduce the number of Shares available for issuance under Section 5.

(e) **Modification or Assumption of Restricted Stock Grants.** Within the limitations of the Plan, the Committee may modify or assume outstanding Restricted Stock Grants or may accept the cancellation of outstanding Restricted Stock Grants (including stock granted by another issuer) in return for the grant of new Restricted Stock Grants for the same or a different number of Shares. No modification of a Restricted Stock Grant shall, without the consent of the Participant, impair his or her rights or increase his or her obligations under such Restricted Stock Grant.

(f) **Assignment or Transfer of Restricted Stock Grants.** Except as provided in Section 14, or in a Restricted Stock Grant Agreement, or as required by applicable law, a Restricted Stock Grant awarded under the Plan shall not be anticipated, assigned, attached, garnished, optioned, transferred or made subject to any creditor's process, whether voluntarily, involuntarily or by operation of law. Any act in violation of this Section 9(f) shall be void. However, this Section 9(f) shall not preclude a Participant from designating a beneficiary pursuant to Section 4(d) nor shall it preclude a transfer of Restricted Stock Grant Awards by will or pursuant to Section 4(d).

SECTION 10. TERMS AND CONDITIONS FOR STOCK UNITS.

(a) **Stock Unit Agreement.** Each grant of Stock Units under the Plan shall be evidenced by a Stock Unit Agreement between the Participant and the Company. Such Stock Units shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan (including without limitation any performance conditions). The provisions of the various Stock Unit Agreements entered into under the Plan need not be identical. Stock Units may be granted in consideration of a reduction in the Participant's other compensation.

(b) **Number of Shares and Payment.** Each Stock Unit Agreement shall specify the number of Shares to which the Stock Unit Award pertains and is subject to adjustment of such number in accordance with Section 11. To the extent that an Award is granted in the form of Stock Units, no cash consideration shall be required of the Award recipients.

(c) **Vesting Conditions.** Each Award of Stock Units may or may not be subject to vesting. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the Stock Unit Agreement. A Stock Unit Agreement may provide for accelerated vesting in the event of the Participant's death, or Disability or other events.

(d) **Voting and Dividend Rights.** The holders of Stock Units shall have no voting rights. Prior to settlement or forfeiture, any Stock Unit awarded under the Plan may, at the Committee's discretion, carry with it a right to dividend equivalents. Such right entitles the holder to be credited with an amount equal to all cash or Common Stock dividends paid on one Share while the Stock Unit is outstanding. Dividend equivalents may be converted into additional Stock Units. Settlement of dividend equivalents may be made in the form of cash, in the form of Shares, or in a combination of both. Prior to vesting of the Stock Units, any dividend equivalents accrued on such unvested Stock Units may be subject to the same vesting conditions and restrictions as the Stock Units to which they attach.

(e) **Modification or Assumption of Stock Units.** Within the limitations of the Plan, the Committee may modify or assume outstanding Stock Units or may accept the cancellation of outstanding Stock Units (including stock units granted by another issuer) in return for the grant of new Stock Units for the same or a different number of Shares. No modification of a Stock Unit shall, without the consent of the Participant, impair his or her rights or increase his or her obligations under such Stock Unit.

(f) **Assignment or Transfer of Stock Units.** Except as provided in Section 14, or in a Stock Unit Agreement, or as required by applicable law, Stock Units shall not be anticipated, assigned, attached, garnished, optioned, transferred or made subject to any creditor's process, whether voluntarily, involuntarily or by operation of law. Any act in violation of this Section 10(f) shall be void. However, this Section 10(f) shall not preclude a Participant from designating a beneficiary pursuant to Section 4(d) nor shall it preclude a transfer of Stock Units pursuant to Section 4(d).

(g) **Form and Time of Settlement of Stock Units.** Settlement of vested Stock Units may be made in the form of (a) cash, (b) Shares or (c) any combination of both, as determined by the Committee. The actual number of Stock Units eligible for settlement may be larger or smaller than the number included in the original Award. Methods of converting Stock Units into cash may include (without limitation) a method based on the average Fair Market Value of Shares over a series of trading days. Except as otherwise provided in a Stock Unit Agreement or a timely completed deferral election, vested Stock Units shall be settled within thirty (30) days after vesting. The distribution may occur or commence when all vesting conditions applicable to the Stock Units have been satisfied or have lapsed, or it may be deferred, in accordance with applicable law, to a later specified date. The amount of a deferred distribution may be increased by an interest factor or by dividend equivalents. Until an Award of Stock Units is settled, the number of such Stock Units shall be subject to adjustment pursuant to Section 11.

(h) **Creditors' Rights.** A holder of Stock Units shall have no rights other than those of a general creditor of the Company. Stock Units represent an unfunded and unsecured obligation of the Company, subject to the terms and conditions of the applicable Stock Unit Agreement.

SECTION 11. ADJUSTMENTS.

(a) **Adjustments.** In the event of a subdivision of the outstanding Shares, a declaration of a dividend payable in Shares, a declaration of a dividend payable in a form other than Shares in an amount that has a material effect on the price of Shares, a combination or consolidation of the outstanding Shares (by reclassification or otherwise) into a lesser number of Shares, a stock split, a reverse stock split, a reclassification or other distribution of the Shares without the receipt of consideration by the Company, of or on the Common Stock, a recapitalization, a combination, a spin-off or a similar occurrence, the Committee shall make equitable and proportionate adjustments to:

- (i) the Share Limit and ISO Limit specified in Section 5(a);

- (ii) the number and kind of securities available for Awards (and which can be issued as ISOs) under Section 5;
- (iii) the number and kind of securities covered by each outstanding Award;
- (iv) the Exercise Price under each outstanding Option and SAR and Other Equity Award; and
- (v) the number and kind of outstanding securities issued under the Plan.

(b) **Participant Rights.** Except as provided in this Section 11, a Participant shall have no rights by reason of any issue by the Company of stock of any class or securities convertible into stock of any class, any subdivision or consolidation of shares of stock of any class, the payment of any stock dividend or any other increase or decrease in the number of shares of stock of any class. If by reason of an adjustment pursuant to this Section 11, a Participant's Award covers additional or different shares of stock or securities, then such additional or different shares and the Award in respect thereof shall be subject to all of the terms, conditions and restrictions which were applicable to the Award and the Shares subject to the Award prior to such adjustment.

(c) **Fractional Shares.** Any adjustment of Shares pursuant to this Section 11 shall be rounded down to the nearest whole number of Shares. Under no circumstances shall the Company be required to authorize or issue fractional shares. To the extent permitted by applicable law, no consideration shall be provided as a result of any fractional shares not being issued or authorized.

SECTION 12. EFFECT OF A CHANGE IN CONTROL.

(a) **Merger or Reorganization.** In the event that there is a Change in Control and/or the Company is a party to a merger or acquisition or reorganization or Change in Control Event or similar transaction, outstanding Awards shall be subject to the merger agreement or other applicable transaction agreement. Such agreement may provide, without limitation, that subject to the consummation of the applicable transaction, for the assumption (or substitution) of outstanding Awards by the surviving corporation or its parent, for their continuation by the Company (if the Company is a surviving corporation), for accelerated vesting or for their cancellation with or without consideration, or for the mandatory exercise or conversion of Awards into Shares and/or cash whether by Net Exercise or otherwise, in all cases without the consent of the Participant.

(b) **Acceleration of Vesting.** In the event that a Change in Control occurs and there is no assumption, substitution or continuation of Awards pursuant to Section 12(a), the Committee in its discretion may provide that some or all Awards shall vest and become exercisable in connection with such Change in Control. For avoidance of doubt, "substitution" includes, without limitation, an Award being replaced by a cash award that provides an equivalent intrinsic value (wherein intrinsic value equals the difference between the market value of a share and any exercise price). The Committee may also in its discretion include in an Award Agreement a requirement that, under certain circumstances, acceleration of vesting (or compensation payable) with respect to such Award shall be reduced (or eliminated) to the extent that such reduction (or elimination) would, after taking into account any other payments in the nature of compensation to which the Participant would have a right to receive from the Company and any other person contingent upon the occurrence of a Change in Control, prevent the occurrence of a "parachute payment" as defined under Code Section 280G.

SECTION 13. LIMITATIONS ON RIGHTS.

(a) **Retention Rights.** Neither the Plan nor any Award granted under the Plan shall be deemed to give any individual a right to remain in Service as an Employee, Consultant, or Non-Employee Director of the Company, a Parent, a Subsidiary or an Affiliate or to receive any future Awards under the Plan. The Company and its Parents and Subsidiaries and Affiliates reserve the right to terminate the Service of any person at any time, and for any reason, subject to applicable laws, the Company's Bylaws and Charter and a written employment agreement (if any).

(b) **Regulatory Requirements.** Any other provision of the Plan notwithstanding, the obligation of the Company to issue Shares or other securities under the Plan shall be subject to all applicable laws, rules and regulations and such approval by any regulatory body as may be required. The Company reserves the right to restrict, in whole or in part, the delivery of Shares or other securities pursuant to any Award prior to the satisfaction of all legal requirements relating to the issuance of such Shares or other securities, to their registration, qualification or listing or to an exemption from registration, qualification or listing.

(c) **Dissolution.** To the extent not previously exercised or settled, all Options, SARs, Stock Units, Cash Awards, Other Equity Awards and unvested Restricted Stock Grants shall terminate immediately prior to the dissolution or liquidation of the Company and shall be forfeited to the Company without consideration (except for repayment of any amounts a Participant had paid to the Company to acquire unvested Shares underlying the forfeited Awards).

(d) **Clawback Policy.** The Company may (i) cause the cancellation of any Award, (ii) require reimbursement of any Award by a Participant and (iii) effect any other right of recoupment of equity or other compensation provided under this Plan or otherwise in accordance with Company policies and/or applicable law (each, a "Clawback Policy"). In addition, a Participant may be required to repay to the Company certain previously paid compensation, whether provided under this Plan or an Award Agreement or otherwise, in accordance with the Clawback Policy. By accepting an Award, a Participant is also agreeing to be bound by the Company's Clawback Policy which may be amended from time to time by the Company in its discretion (including without limitation to comply with applicable laws or stock exchange requirements) and is further agreeing that all of the Participant's Awards may be unilaterally amended by the Company to the extent needed to comply with the Clawback Policy.

SECTION 14. WITHHOLDING TAXES.

(a) **General.** A Participant shall make arrangements satisfactory to the Company for the satisfaction of any withholding tax obligations that arise in connection with his or her Award. The Company shall not be required to issue any Shares or make any cash payment under the Plan until such obligations are satisfied and the Company shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the Participant.

(b) **Share Withholding.** The Committee in its discretion may permit or require a Participant to satisfy all or part of his or her withholding tax obligations by having the Company withhold all or a portion of any Shares that otherwise would be issued to him or her or by surrendering all or a portion of any Shares that he or she previously acquired (or by stock attestation). Such Shares shall be valued based on the value of the actual trade or, if there is none, the Fair Market Value as of the previous day. Any payment of taxes by assigning Shares to the Company may be subject to restrictions, including, but not limited to, any restrictions required by rules of the SEC. The Committee may also, in its discretion, permit or require a Participant to satisfy withholding tax obligations related to an Award through a sale of Shares underlying the Award or, in the case of Options, through Net Exercise or Cashless Exercise. The number of Shares that are withheld from an Award pursuant to this section may also be limited by the Committee, to the extent necessary, to avoid liability-classification of the Award (or other adverse accounting treatment) under applicable financial accounting rules including without limitation by requiring that no amount may be withheld which is in excess of the applicable maximum statutory withholding rates. The Committee, in its discretion, may permit other forms of payment of applicable tax withholding.

SECTION 15. DURATION AND AMENDMENTS.

(a) **Term of the Plan.** The Plan, as set forth herein, is effective on the Adoption Date. The Plan shall terminate on the day before the tenth (10th) anniversary of the Adoption Date and may be terminated on any earlier date pursuant to this Section 15. This Plan will not in any way affect outstanding awards that were issued under any other Company equity compensation plans.

(b) **Right to Amend or Terminate the Plan.** The Board may amend or terminate the Plan at any time and for any reason. No Awards shall be granted under the Plan after the Plan's termination. An amendment of the Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, regulations or rules. In addition, no such amendment or termination (or amendment of an executed Award Agreement) shall be made which would materially impair the rights of any Participant, without such Participant's written consent, under any then-outstanding Award. In the event of any conflict in terms between the Plan and any Award Agreement, the terms of the Plan shall prevail and govern.

SECTION 16. EXECUTION.

To record the adoption of the Plan by the Board, the Company has caused its duly authorized Officer to execute this Plan on behalf of the Company.

GREENWICH LIFE SCIENCES, INC.

By:

Name: Snehal Patel

Title: Chief Executive Officer

INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (the “*Agreement*”) is made and entered into as of _____, between Greenwich LifeSciences, Inc., a Delaware corporation (the “*Company*”), and _____ (“*Indemnitee*”).

WITNESSETH THAT:

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors, officers, managers, or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors of the Company (the “*Board*”) has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, managers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (“*DGCL*”). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the Board, officers, managers, and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent not prohibited by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder;

WHEREAS, Indemnitee does not regard the protection available under the Company's Certificate of Incorporation and insurance as necessarily adequate in the present circumstances, and may not be willing to serve as an officer, director, or manager without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified; and

NOW, THEREFORE, in consideration of Indemnitee's agreement to serve as a director, officer, manager, or in other capacities from and after the date hereof, the parties hereto agree as follows:

1. Indemnity of Indemnitee. The Company shall hold harmless and indemnify Indemnitee to the fullest extent not prohibited by applicable law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof.

(a) Proceedings Other Than Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Section 1(a) if, by reason of his Corporate Status (as hereinafter defined), the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (as hereinafter defined) other than a Proceeding by or in the right of the Company. Pursuant to this Section 1(a), Indemnitee shall be indemnified against all Expenses (as hereinafter defined), judgments, penalties, fines and amounts paid in settlement actually incurred by him in connection with such Proceeding or any claim, issue or matter therein, unless a court having jurisdiction in the matter shall determine that such indemnification is prohibited by applicable law.

(b) Proceedings by or in the Right of the Company. Indemnatee shall be entitled to the rights of indemnification provided in this Section 1(b) if, by reason of his Corporate Status, the Indemnatee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this Section 1(b), Indemnatee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnatee, or on the Indemnatee's behalf, in connection with such Proceeding, unless a court having jurisdiction in the matter shall determine that such indemnification is prohibited by applicable law.

(c) Indemnification for Expenses of a Party Who is Wholly or Partly Successful Notwithstanding any other provision of this Agreement, to the extent that Indemnatee is, by reason of his Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, he shall be indemnified to the maximum extent not prohibited by applicable law, as such may be amended from time to time, against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith. If Indemnatee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnatee against all Expenses actually and reasonably incurred by him or on his behalf to the extent relating to each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Agreement, the Company shall and hereby does indemnify and hold harmless Indemnatee against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf if, by reason of his Corporate Status, he is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnatee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnatee unless a court having jurisdiction in the matter shall determine that such indemnification is prohibited by applicable law.

3. Contribution.

(a) Whether or not the indemnification provided in Sections 1 and 2 hereof is available, in respect of any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such action, suit or proceeding without requiring Indemnitee to contribute to such payment and, to the fullest extent not prohibited by applicable law, the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors, managers, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such action, suit or proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors, managers, or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. To the fullest extent not prohibited by applicable law, the relative fault of the Company and all officers, directors, managers, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.

(c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors, managers, or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.

(d) If the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by or on behalf of Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding and/or (ii) the relative fault of the Company (and its directors, officers, managers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

4. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.

5. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee's Corporate Status within ten (10) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee and shall include or be preceded or accompanied by a written undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it shall ultimately be determined by a court having jurisdiction of the matter that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 5 shall be unsecured and interest free.

6. Liability Insurance. For the duration of Indemnatee's service as a director or officer or other agent of the Company, and thereafter for as long as Indemnatee shall be subject to any pending or possible Proceeding by reason of his Corporate Status, the Company shall cause to be maintained in effect policies of liability insurance providing for coverage of directors and officers of the Company in an amount of at least \$5,000,000 with an A rated insurer providing for Side A coverage (with no deductibles). To the extent the Company maintains liability insurance applicable to directors, officers, employees, agents or fiduciaries, Indemnatee shall be covered by such policies in such a manner as to provide Indemnatee the same rights and benefits as are provided to the most favorably insured of the Company's directors.

7. Remedies of Indemnatee.

(a) In the event that Indemnatee seeks a judicial adjudication of his rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company shall pay on his behalf, in advance, any and all expenses (of the types described in the definition of Expenses in Section 13 of this Agreement) actually and reasonably incurred by him in such judicial adjudication, regardless of whether Indemnatee ultimately is determined to be entitled to such indemnification, advancement of expenses or insurance recovery.

(b) To the fullest extent not prohibited by applicable law, the Company shall be precluded from asserting in any judicial proceeding that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. The Company shall indemnify Indemnatee against any and all Expenses and, if requested by Indemnatee, shall (within five (5) days after receipt by the Company of a written request therefore) advance, to the fullest extent not prohibited by applicable law, such expenses to Indemnatee, which are incurred by Indemnatee in connection with any action brought by Indemnatee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnatee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.

(c) The knowledge or actions, or failure to act, of any director, officer, agent or employee of the Company or the Company itself shall not be imputed to Indemnatee for purposes of determining any rights to indemnification under this Agreement.

8. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation.

(a) The rights of indemnification as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnatee may at any time be entitled under applicable law, the Certificate of Incorporation, any agreement, a vote of stockholders, a resolution of directors of the Company, or otherwise. In the event of any conflict or inconsistency between the Certificate of Incorporation of the Company and this Agreement, this Agreement shall control to the extent not prohibited by applicable law. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnatee under this Agreement in respect of any action taken or omitted by such Indemnatee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnatee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, managers, employees, or agents or fiduciaries of the Company or of any other Enterprise that such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, manager, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

9. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of state statutory law or common law; or

(c) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, managers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, or (iii) the action is brought to enforce or establish a right to indemnification under this Agreement or otherwise.

10. Duration of Agreement. All agreements and obligations of the Company contained herein shall continue during the period Indemnitee is an officer, director, or manager of the Company (or is or was serving at the request of the Company as a director, officer, manager, employee or agent of another Enterprise) and shall continue thereafter (a) for seven (7) years, or if applicable after such seven (7) year period, (b) for so long as Indemnitee shall be subject to any Proceeding (or any proceeding commenced under Section 7 hereof) by reason of his Corporate Status, whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors and personal and legal representatives.

11. Security. To the extent requested by Indemnitee and approved by a vote of disinterested directors in their sole discretion, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

12. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby in order to induce Indemnitee to serve as an officer, director, or manager of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as an officer, director, or manager of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.

(c) The Company shall not seek from a court, or agree to, a “**bar order**” which would have the effect of prohibiting or limiting the Indemnitee’s rights to receive advancement of expenses under this Agreement.

13. Definitions. For purposes of this Agreement:

(a) “**Corporate Status**” describes the status of a person who is or was a director, officer, manager, employee, agent or fiduciary of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the express written request of the Company.

(b) “**Expenses**” shall include all reasonable attorneys’ fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also shall include Expenses incurred in connection with any appeal resulting from any Proceeding and any federal, state, local or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, including without limitation the premium, security for, and other costs relating to any cost bond, supersede as bond, or other appeal bond or its equivalent. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(c) “**Proceeding**” includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of his or her Corporate Status, by reason of any action taken by him or of any inaction on his part while acting in his or her Corporate Status; in each case whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 7 of this Agreement to enforce his rights under this Agreement.

14. Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Further, the invalidity or unenforceability of any provision hereof as to either Indemnitee or Appointing Stockholder shall in no way affect the validity or enforceability of any provision hereof as to the other. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee and Appointing Stockholder indemnification rights to the fullest extent not prohibited by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision shall be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.

15. Modification and Waiver. No supplement, modification, termination or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.

16. Notice By Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.

17. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile or email if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. For the avoidance of doubt, any form of written communication will also be scanned and sent by email to the email address of the respective parties. All communications shall be sent to the Company at:

Greenwich LifeSciences, Inc.
2311 Spartan Trail
Sugar Land, TX 77479
Attn: Snehal Patel
Telephone: (203) 434-3290
Email: snehalpatel2@yahoo.com

or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.

18. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

19. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

20. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the “**Delaware Court**”), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum. 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.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement on and as of the day and year first above written.

INDEMNITEE(S):

COMPANY:
GREENWICH LIFESCIENCES, INC.

By:
Name:

By:
Name:
Title:

Date:

Date:



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Form S-1 of our report dated April 2, 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
 May 29, 2020

9801 Westheimer Road, Suite 1100, Houston, Texas 77042 713.343.4286

Zhongzhou Holdings Financial Center (Tower B) #2205 No. 88, Haide Yi Road, Nanshan District, Shenzhen, P.R. China 518054 86.755.8627.8659

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www.malonebailey.com

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