

**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

(State or other jurisdiction of
incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

20-5473709

(I.R.S. Employer
Identification Number)

**2311 Spartan Trail
Sugar Land, TX 77479
(832) 819-3232**

(Address and telephone number of registrant's principal executive offices)

**Snehal Patel
Chief Executive Officer
Greenwich LifeSciences, Inc.
2311 Spartan Trail
Sugar Land, TX 77479
(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 ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price¹	Amount of Registration Fee²
Common Stock, par value \$0.001 per share	\$	\$

- (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.

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.

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 , 2020

PROSPECTUS

Shares



Common Stock

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 intend to apply to list our shares on The Nasdaq Capital Market under the symbol “GLS.”

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 7.

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

(1) We refer you to “Underwriting” beginning on page 90 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters a -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

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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. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

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 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," "GLS" "Greenwich LifeSciences," or "the Company" refer to Greenwich LifeSciences, Inc.

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 (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

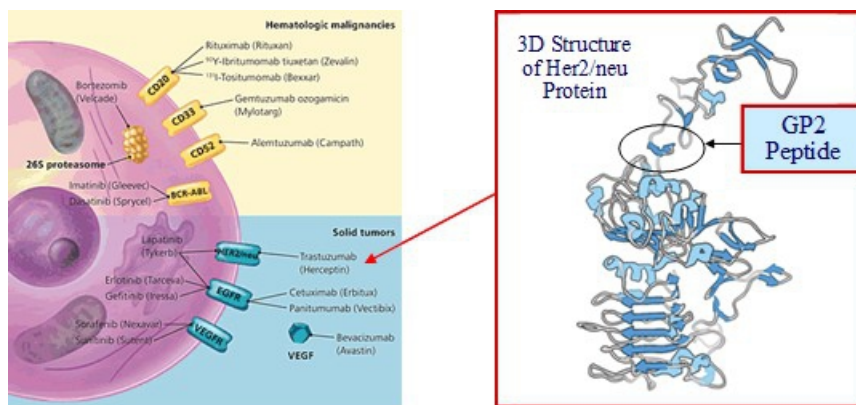
The Henry M. Jackson Foundation, or HJF, is the licensing arm of the United States military and it conducts research and manages clinical trials. We entered into an exclusive license agreement with HJF pursuant to which we have been granted an exclusive worldwide license to GP2. The GP2 issued patents provide protection through 2026-2032 in major markets such as the U.S., Europe, Japan, Australia, and Canada, with ongoing prosecution in emerging markets. We plan to register GP2 as a Biologic, subject to 10-12 years data 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.

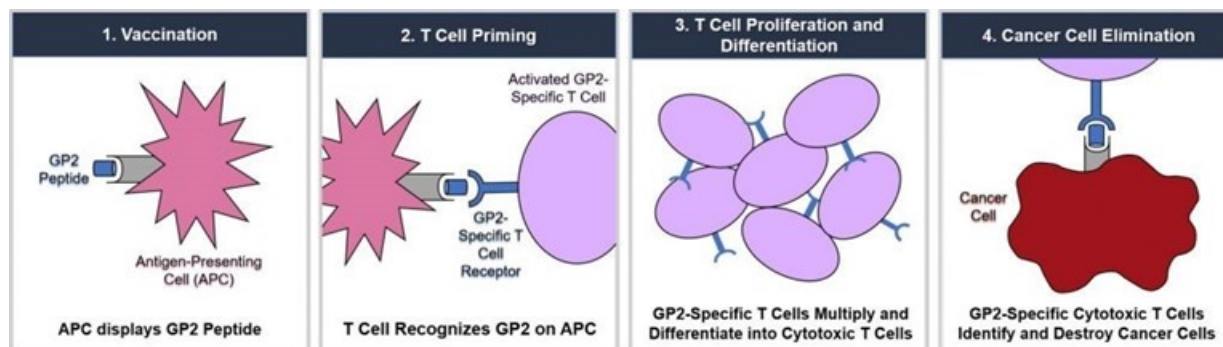
Our Product Candidate

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 license agreements, we may lose the ability to develop our product candidates.
- 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 product candidates in clinical development. If we are unable to successfully develop and commercialize product candidates or experiences 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 candidates.

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 2311 Spartan Trail, Sugar Land, TX 77479 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 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 candidates, 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.
Risk factors	See “Risk Factors” on page 7 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	“GLS”

The number of shares of our common stock to be outstanding after this offering is based on 22,582,889 shares of our common stock outstanding as of December 31, 2019, and excludes as of that date:

- 4,060,896 shares of common stock issuable upon conversion of our Series A Preferred Stock;
- 345,132 shares of common stock issuable upon conversion of our Series B Preferred Stock;
- 177,750 shares of common stock issuable upon conversion of our Series C Preferred Stock;
- 703,762 shares of common stock issuable upon conversion of our Series D Preferred Stock;
- 2,217,925 shares of common stock subject to future vesting issued to members of management and directors; and
- 4,000,000 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan.

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, 2018 and 2017 from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the nine months ended September 30, 2019 and 2018 and the summary balance sheet data as of September 30, 2019 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 nine months ended September 30, 2019 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,		For the Nine Months Ended September 30, (unaudited)	
	2018	2017	2019	2018
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses				
Research and development	1,270	1,223	2,348	109
General and administrative	420	350	741	25
Total operating expenses	1,690	1,573	3,089	134
Net loss	\$ (1,690)	\$ (1,573)	\$ (3,089)	\$ (134)
Net loss per common share—basic and diluted ¹	\$ (3.12)	\$ (2.90)	\$ (4.97)	\$ (0.25)
Weighted average common shares outstanding—basic and diluted ¹	541,991	541,991	621,658	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)

	September 30, 2019 (unaudited)		
	Actual	Pro Forma ⁽¹⁾	Pro Forma, As Adjusted ⁽²⁾⁽³⁾
Cash	\$ 6	\$	\$
Working capital deficit	(1,230)		
Total assets	27		
Total liabilities	1,236		
Accumulated deficit	(26,877)		
Total stockholders' deficit	(1,209)		

(1) On a pro forma basis to reflect the issuance of 25,000 shares of common stock in December 2019 in consideration for services.

(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 nine months ended September 30, 2019 and the years ended December 31, 2018 and 2017, we reported a net loss of \$3.1 million, \$1.7 million and \$1.6 million, respectively. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of \$26.9 million and \$23.8 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 candidates 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 candidates;
- 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 candidates. 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 September 30, 2019 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 any of our product candidates, 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 candidates 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.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned development programs for our product candidates, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our product candidates in any indication;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if our clinical trials are successful;
- the cost of commercialization activities for our product candidates, if any of these product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates 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 one or more of our product candidates 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 candidates.

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 candidates 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, and for our subsidiaries to guarantee our obligations. 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, products or product candidates 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 September 30, 2019, we had cash of \$6,002. In addition, we had current liabilities of approximately \$1.2 million. We expect our existing cash as of September 30, 2019 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, 2018 and 2017 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 candidates, 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 candidates, 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 products, 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 candidates;
- develop commercial quantities of our product candidates, once approved, at acceptable cost levels; obtain additional funding, if required to develop and commercialize our product candidates;
- 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 products;
- 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, 2018, we had federal net operating loss carryforwards of approximately \$2.8 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 Candidates

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

We are currently a clinical-stage biopharmaceutical company with product candidates in clinical development. The success of our product candidates 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 candidates or product candidates we are interested in in-licensing or acquiring, including product candidates;
- designing, conducting and completing clinical trials for our product candidates with positive results;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- 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 candidates at an acceptable cost;
- effectively launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- achieving acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our products candidates are approved, obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates;
- 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 products during development and following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products 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 candidates, 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 candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.

Identifying and qualifying patients to participate in clinical trials of our current and future product candidates 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 candidates, 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 candidates 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 candidates 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 candidates 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 current or future product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates 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 candidates 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. Any of our product candidates that are in, or may advance to, clinical trials may not succeed in clinical trials despite promising preclinical data.

Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, 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 candidates 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 candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our current or 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 any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates 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 candidates. In particular, clinical trials of our product candidates 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 any of our product candidates 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 candidates, the approval and commercial prospects of such product candidates 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 products may be decreased. Regulatory approval of our product candidates may be denied for the same reasons that caused the delay.

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

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

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the U.S., e.g., General Data Protection Regulation in the European Union;

- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials by the FDA or other comparable foreign regulatory authorities; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human subjects. As a result of safety or toxicity issues that we may experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates similar to our own, we may not receive approval to market any product candidates, 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 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 any of our product candidates 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 products;
- 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 the particular product candidate, if approved.

Our product development program may not uncover all possible adverse events that patients who take our product candidates may experience. The number of subjects exposed to product candidates 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 candidates will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to our product candidates. If such safety problems occur or are identified after our product candidates 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 candidates.

Our business is dependent on our ability to obtain regulatory approval for our product candidates in a timely manner. We cannot commercialize product candidates in the U.S. without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any 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 or future product candidates, once obtained, may be withdrawn.

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

We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidates 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 candidates 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 any of our product candidates 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 one of our product candidates 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 candidates from being marketed abroad.

In addition to regulations in the U.S., to market and sell our product candidates 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 products in any market. If we are unable to obtain approval of any of our current or future product candidates 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 and future product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a 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 any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a 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 candidates or the manufacturing facilities for our product candidates 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 products and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the U.S. will be 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. will be heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our products 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 candidates 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 candidates, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail.

Both the active pharmaceutical ingredient and drug product for our product candidates are currently single sourced. We believe these single sources are currently capable of supplying all anticipated needs of our proposed clinical studies, as well as initial commercial introduction. If we are able to commercialize our products 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 candidates, 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 candidates.

We and our CMOs will need to conduct significant development work for each 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 candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors.

Additionally, the process of manufacturing our product candidates 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 candidates or in the manufacturing facilities in which our product candidates are 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 candidates 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 candidates. 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 candidates could damage our reputation and the reputation of our products 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 candidates 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 candidates.

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 any future product candidates and programs because our research and development pipeline may be insufficient, our 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 our 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 product candidates could also delay the development and commercialization of our 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 some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, CROs and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, and to conduct clinical trials for some or all of our product candidates. 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 candidates. 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 candidates. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our research and development programs, product candidates or potential product candidates, 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 candidates infringe upon the intellectual property rights of those third parties. Any assertion by third parties that our activities or product candidates infringe upon the intellectual property rights of third parties may adversely affect our ability to secure strategic partners or licensees for our technology or product candidates 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 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 candidates, 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 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. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates 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 candidates, but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;

- our pending patent applications may not result in issued patents;
- the claims of our issued patents or patent applications when issued may not cover our products or product candidates;
- any patents that we obtain may not provide us with any competitive advantages;
- any granted patents 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 the affected product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. 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 one or more of our product candidates, 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 our patents, that party will have the right to ask the examiner or court to rule that our patents are invalid or should not be enforced against them. There is a risk that the examiner or court will decide that our patents are not valid and that we do 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 our 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 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 candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, 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 candidates. 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 the relevant 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 products 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 candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were 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 our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed U.S. patent applications on inventions similar to ours that claims priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. 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 we can 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 products 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 products 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 products or future products.

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 products; 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 candidates in the future. There can be no assurance that we will be able to successfully defend patents we own 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 our patents and those 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 our patent protection could be reduced or eliminated for non-compliance with these requirements.

Risks Related to Commercialization of Our Current and Future Product Candidates

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

Even if we obtain regulatory approval for any of our current or 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 products as well as competitive products;
- the development of manufacturing and distribution processes for commercial scale manufacturing for our 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 any of our current and 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 or 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 these products 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 products 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 products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products 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 products 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 candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- 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 candidates, 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 candidates 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 products 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 products. 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 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 products. If we cannot successfully defend ourselves against claims that our product candidates or products 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 candidates 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 candidates. 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 or future product candidates, 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 candidates could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. 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 products 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 those product candidates 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 or future product candidates. 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 candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

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 September 30, 2019, we had no full-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 candidates. 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 candidates 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.

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;
- 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 candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;
- 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 candidates;
- unanticipated safety concerns related to the use of our product candidates;
- 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 products, or continue our operations.

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

Concerns over inflation, 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 going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, 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 September 30, 2019 of \$. 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 products, 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 intend to apply 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 lead underwriter, , is not obligated to make a market in our common stock, and even after making a market, can discontinue market making at any time without notice. Neither we nor the underwriters can provide any assurance that an active and liquid trading market in our common stock will develop or, if developed, that the market will continue.

Our certificate of incorporation and our bylaws, 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 the 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 September 30, 2019, 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.

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 candidates;
- the potential that results of preclinical and clinical trials indicate our current product candidates 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 candidates;
- 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 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 these claims;
- 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 candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates 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 from this offering for clinical trials, manufacturing our product candidates, including GP2, retention of CROs to conduct clinical trials, 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.

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 product candidates 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 candidates 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 September 30, 2019:

- on an actual basis; 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	Pro Forma, As Adjusted ¹ (unaudited)
Cash	\$ 6	\$
Short term notes payable to related parties	420	
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	
Common stock, par value \$0.001 per share; 100,000,000 shares authorized, 22,350,814 shares issued and outstanding, actual; _____ shares authorized, _____ shares issued and outstanding, pro forma; _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted	22	
Additional paid-in capital	25,641	
Accumulated deficit	(26,877)	
Total stockholders' deficit	(1,209)	
Total capitalization	\$ (1,209)	\$

- (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.

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 September 30, 2019 we had a historical net tangible book value (deficit) of \$(1,229,564), or \$(0.06) per share of common stock, based on shares of common stock outstanding at September 30, 2019. Our historical net tangible book value per share is the amount of our total tangible assets less our total liabilities at September 30, 2019, divided by the number of shares of common stock outstanding at September 30, 2019.

Our pro forma net tangible book value as of September 30, 2019 was \$, or \$ 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 September 30, 2019 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	\$
Net tangible book value per share as of September 30, 2019	\$
Increase in net tangible book value per share attributable to new investors in this offering	<u> </u>
Pro forma as adjusted net tangible book value per share immediately after this offering	<u> </u>
Dilution per share to new investors in this offering	<u>\$</u>

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 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	
	Number	Percentage	Amount	Percentage	Per Share	
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, new stock options are issued 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, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. 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, 2018 and 2017 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2019 and 2018 and the balance sheet data as of September 30, 2019 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 nine months ended September 30, 2019 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,		Nine Months Ended September, (unaudited)	
	2018	2017	2019	2018
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses				
Research and development	1,270	1,223	2,348	109
General and administrative	420	350	741	25
Total operating expenses	1,690	1,573	3,089	134
Net loss	\$ (1,690)	\$ (1,573)	\$ (3,089)	\$ (134)
Net loss per common share—basic and diluted ¹	\$ (3.12)	\$ (2.90)	\$ (4.97)	\$ (0.25)
Weighted average common shares outstanding—basic and diluted ¹	541,991	541,991	621,658	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,		September 30,
	2018	2017	2019 (unaudited)
Cash	\$ 85	—	\$ 6
Working capital deficit	(643)	(557)	(1,230)
Total assets	109	27	27
Total liabilities	10,229	8,558	1,236
Accumulated deficit	(23,789)	(22,099)	(26,877)
Total stockholders' deficit	(10,120)	(8,530)	(1,209)
Total liabilities and stockholders' deficit	109	27	27

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN 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 \$1.7 million and \$1.6 million for the years ended December 31, 2018 and 2017, respectively, and approximately \$3.1 million and \$0.1 million for the nine months ended September 30, 2019 and 2018, respectively.

Our net losses have resulted from costs incurred in developing the drugs 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 candidates. 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, 2018 and 2017

Research and Development Expenses

Research and development expenses increased by \$46,965, or 4%, to \$1,270,016 for the year ended December 31, 2018 from \$1,223,051 for the year ended December 31, 2017.

General and Administrative Expenses

General and administrative expenses increased by \$69,220, or 20% to \$419,639 for the year ended December 31, 2018 from \$350,419 for the year ended December 31, 2017. The increase was primarily the result of an increase in compensation expense.

Results of Operations For the Nine Months Ended September 30, 2019 and 2018

Research and Development Expenses

Research and development expenses increased by \$2,239,074, or 2,060%, to \$2,347,746 for the nine months ended September 30, 2019 from \$108,672 for the nine months ended September 30, 2018. The increase was primarily the result of an increase and timing differences in related party compensation expense and increased manufacturing expense for GP2 for the planned clinical trial.

General and Administrative Expenses

General and administrative expenses increased by \$715,913, or 2,851%, to \$741,025 for the nine months ended September 30, 2019 from \$25,112 for the nine months ended September 30, 2018. The increase was primarily the result of an increase and timing differences in related party compensation expense.

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 products 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 September 30, 2019, our principal source of liquidity was our cash, which totaled \$6,002, 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, 2018 and 2017

We incurred net losses of \$1,689,655 and \$1,573,470 during the years ended December 31, 2018 and 2017, respectively, and the increase was primarily due to an increase in compensation expense. Cash was \$54 at December 31, 2017 and \$85,102 at December 31, 2018 and increased due to the following reasons:

Operating Activities

Net cash used in operating activities was \$114,952 for the year ended December 31, 2018 and \$120,847 for the year ended December 31, 2017.

Investing Activities

We did not use or generate cash from investing activities during the year ended December 31, 2018 and December 31, 2017.

Financing Activities

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. Net cash used by financing activities was \$129,846 during the year ended December 31, 2017, as a result of us buying back preferred stock as part of a transfer process between brokerage firms and for the repayment of a related party loan.

Cash Flow Activities for the Nine Months Ended September 30, 2019 and 2018

We incurred net losses of \$3,088,771 and \$133,784 during the nine month periods ended September 30, 2019 and 2018, respectively, and the increase was primarily due to an increase in accounts payable, accrued interest, accrued unreimbursed expenses, and related party payables during the nine month period ended September 30, 2019, which were non-cash expenses.

Operating Activities

Net cash used in operating activities was \$79,100 for the nine months ended September 30, 2019 and \$64,952 for the nine months ended September 30, 2018.

Investing Activities

We did not use or generate cash from investing activities during the nine months ended September 30, 2019 and September 30, 2018.

Financing Activities

We did not use or generate cash from financing activities during the nine months ended September 30, 2019. Net cash provided by financing activities was \$200,000 during the nine months ended September 30, 2018, attributable to the issuance of preferred stock and related party loans.

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.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. 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.

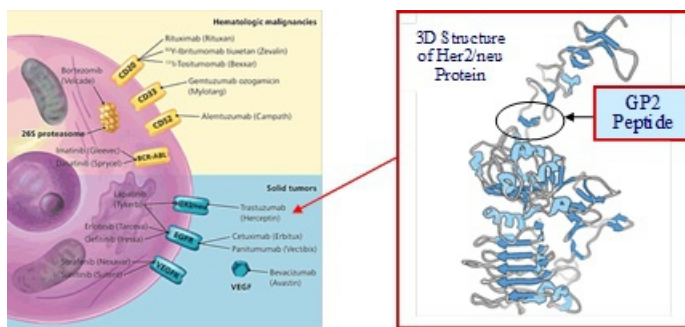
BUSINESS

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.

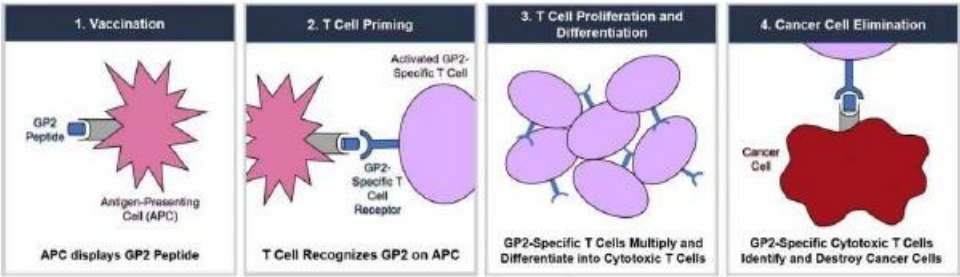
Cancer Immunotherapy

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 malignancies.

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

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

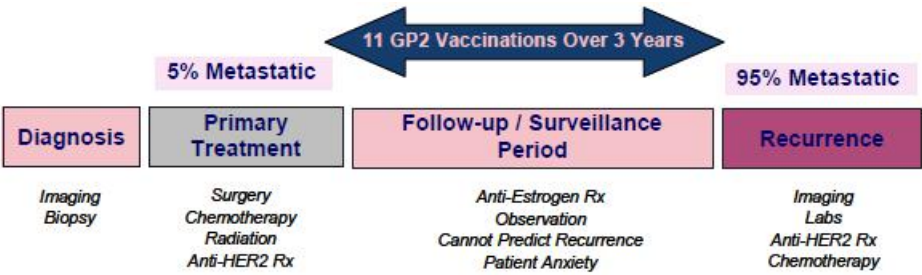


Breast Cancer Treatment Approach – Adjuvant & Neoadjuvant Treatments

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

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

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



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

GP2 Clinical Data & Planned Phase III Trial

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

Clinical Trial Description	Status
<u>GP2 Phase IIb Clinical Trial</u> <ul style="list-style-type: none">Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/neu Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-A02+ Node-Positive and High-Risk Node-Negative Breast Cancer Patients to Prevent Recurrence89 patients treated with GP2 + GM-CSF, 91 placebo patients treated with GM-CSF	Trial Completed
<u>GP2 Phase I Clinical Trial – Combination with AE37</u> <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 Vaccine14 patients treated with GP2 + AE37 + GM-CSF	Trial Completed
<u>GP2 Phase I Clinical Trial – Combination with Trastuzumab</u> <ul style="list-style-type: none">Phase Ib Trial of Combination Immunotherapy with HER2/neu Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients17 patients treated with GP2 + GM-CSF + trastuzumab	Trial Completed
<u>First GP2 Phase I Clinical Trial</u> <ul style="list-style-type: none">Phase Ib Trial of HER2/neu Peptide (GP2) Vaccine in Breast Cancer Patients18 patients treated with GP2 + GM-CSF	Trial Completed

Phase I Clinical Trials

First GP2 Phase I Clinical Trial

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

GP2 Phase I Clinical Trial – Combination with Trastuzumab

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

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

GP2 Phase I Clinical Trial – Combination with AE37

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

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

Phase II Clinical Trial

GP2 Phase IIb Clinical Trial

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

The design of the Phase IIb trial was as follows:

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



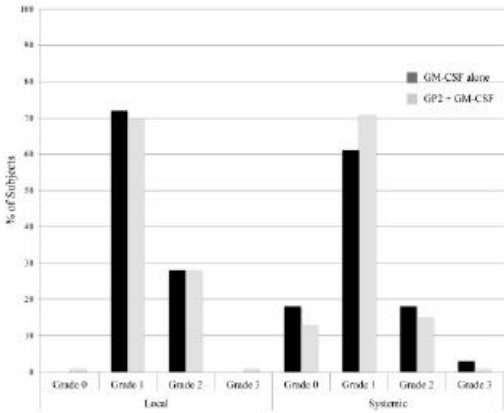
The Phase IIb clinical trial closed in December 2018. The median 5 year follow-up data from this Phase IIb clinical trial is currently being collected and analyzed. The median 5 year data, other than the top-line data described in the table below, has yet to be published.

GP2 + GM-CSF Treated Patients	GM-CSF Placebo Patients			
Recurrence Rate	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. Of the total 180 intent-to-treat patients enrolled, 168 patients completed the 6 primary intradermal injection series over the first 6 months. HER2/neu status was determined based on the expression levels of the HER2/neu protein in each patient using standard of care HER2/neu diagnostic technology. The trial was prospectively designed to analyze these fully treated patients by 2 distinct patient populations, namely HER2/neu 3+ (over expressors) and HER2/neu 1-2+ (low to intermediate expressors):

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

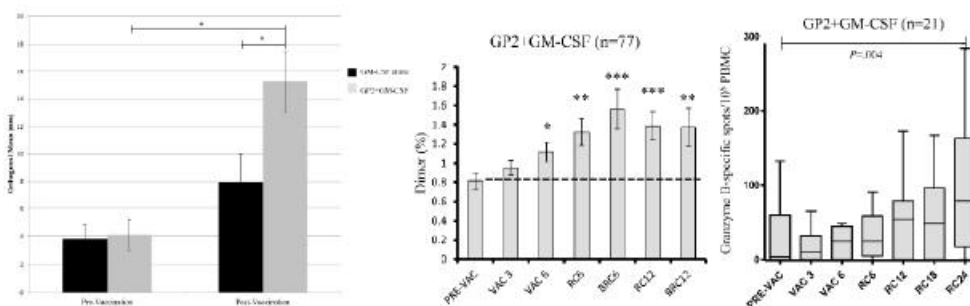
In both patient populations, GP2 was shown to be well tolerated, consisting of primarily injection site reactions which are caused by GM-CSF and can be mitigated by reducing the GM-CSF dose (and then the GP2 dose, if necessary). No SAEs were reported in the GP2 treated patients. Maximum local and systemic toxicities were primarily grade 1 and grade 2. Toxicities ranged from redness at injection site to flu-like symptoms and can be largely attributed to GM-CSF, and not to GP2.



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

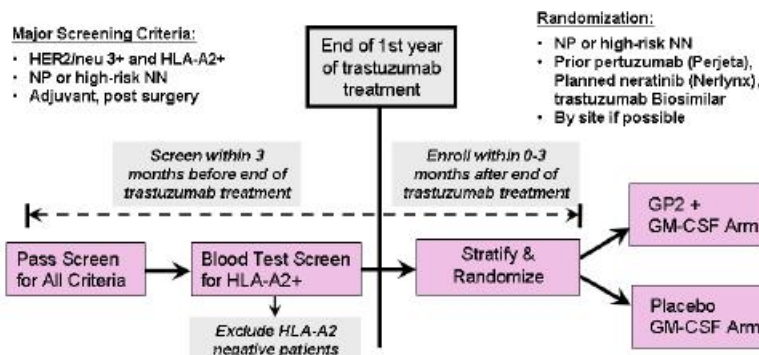
GP2 immunotherapy elicited a potent immune response in HLA-A02 patients after they received the 6 primary intradermal injections over the first 6 months. The immune response was measured by a local skin test and immunological assays. Further, booster injections given every 6 months thereafter prolonged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

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



Planned Phase III Trial

We are planning to launch a Phase III clinical trial in 2020, using a similar treatment regime as the Phase IIb clinical trial. The manufacturing plan and the Phase III trial protocol have been reviewed by the FDA, and final revisions to the Phase III trial protocol are under way, which may include an interim analysis/adaptive trial design. 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.

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; and Daichi Sanko's Enhertu (DS-8201, fam-trastuzumab deruxtecan-nxki). Seattle Genetics' tucatanib is currently under review by the FDA. 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 (atezolimumab). 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.

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 candidates 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 candidates 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 any product candidates.

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 is the licensing arm of the United States military and it conducts research and manages clinical trials. HJF functioned as the CRO for the GP2 Phase IIb clinical trial, managed 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 royalty payments based on the sales of GP2 and to reimburse HJF for patent expenses. The term of the exclusive license shall terminate at such time that the last patent or patent application in the Patent Rights (as defined in the exclusive license agreement) expires or is abandoned, unless terminated earlier pursuant to the terms of the exclusive license agreement.

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 seek 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. It is our policy 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. We also 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 the peptide as a vaccine. The GP2 issued patents provide protection through 2026-2032 in major markets such as the U.S., Europe, Japan, Australia, and Canada, with ongoing prosecution in emerging markets. We plan to register GP2 as a Biologic, subject to 10-12 years data exclusivity in the U.S. upon receiving marketing approval.

The following summarizes the two patent families subject to our exclusive license agreement with HJF:

- GP2 + GM-CSF Patent Family – A patent application has been filed and licensed describing methods 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.
- GP2 + Herceptin Patent Family – A patent application has been filed and licensed describing the method and composition of GP2 peptide in combination with a HER2/neu targeting antibody such as Herceptin. Patent claims describe the method and timing of administration.

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 candidates for one or more indications.

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 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 its current or 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 or 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 its products. 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 products 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 the Health Information Technology and Clinical Health Act, or 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 candidates, 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 candidates. 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 products 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 products, 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 December 31, 2019, 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 December 31, 2019, 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 that we believe could have a material adverse effect on our business, operating results or financial condition.

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 December 31, 2019.

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	76	Chairman of the Board
Eric Rothe	44	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 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. 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 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 and December 31, 2018.

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	2019	-	-	396	-	-	-	16,423	16,819
	2018	-	-	-	-	-	-	-	-
<i>Chief Executive Officer</i>									

(1) For fiscal year 2019, Mr. Patel received shares of the Company's common stock for services rendered and as incentive for services to be rendered.

(2) For fiscal year 2019, Mr. Patel received shares of the Company's common stock in exchange (i) for related party payables for the periods from January 1, 2010 through September 30, 2019 and (ii) for warrants to purchase shares of the Company's 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)	1,604

(1) The Company granted Mr. Patel 2,000,000 shares of common stock on September 30, 2019 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 (\$ (1))	All other compensation (\$ (2))	Total (\$)
David McWilliams	6	1,111	1,117
Eric Rothe	4	781	785
Kenneth Hallock	4	1,938	1,942

(1) Mr. McWilliams, Mr. Rothe, and Mr. Hallock received common stock for services rendered.

(2) Mr. McWilliams, Mr. Rothe, and Mr. Hallock received common stock in exchange (i) for related party payables for the periods from January 1, 2010 through June 30, 2016 and/or (ii) for warrants to purchase shares of common stock.

Employment Agreements

We intend to enter into employment agreements with our management as of the closing of this offering.

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 the Company.

Eligibility to Receive Awards. Employees, consultants and board members of the Company 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 the Company 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 the Company on outstanding awards.

Amendment and Termination of the 2010 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 during our fiscal years ended December 31, 2019 and 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 of the Company, loaned the Company \$15,000 which is payable on demand, is not secured, and does not incur interest, all of which remains outstanding as of December 31, 2019.

On May 30, 2018 and October 2, 2019, the Kenneth and Annette Hallock Revocable Trust loaned the Company \$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 December 31, 2019. Kenneth Hallock, a director of the Company, is one of the Trustees of the Hallock Trust.

Between November 2014 and August 2017, Snehal Patel, Company's Chief Executive Officer and director, loaned the Company 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 December 31, 2019. In addition, as of December 31, 2019, Snehal Patel is owed \$4,817 for reimbursable expenses.

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 and directors owned outstanding warrants to acquire 6,849,909 shares of the Company's 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 the Company's common stock, leaving the Company with no related party payables and no outstanding warrants on September 30, 2019 and December 31, 2019.

Indemnification Agreements

In connection with this offering, we will enter 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 December 31, 2019 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 five percent 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 December 31, 2019, pursuant to the exercise of options or warrants 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 27,870,429 shares of common stock issued and outstanding as of December 31, 2019 after giving effect to the conversion of all outstanding shares of preferred stock and shares of common stock issued and outstanding after the completion of this offering and after giving effect to 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., 2311 Spartan Trail, Sugar Land, TX 77479.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Common Stock Beneficially Owned	
		Before Offering	After Offering
Directors and Executive Officers			
Snehal Patel	21,833,399(1)	80.72%	
F. Joseph Daugherty	74,305(2)	*	
Jaye Thompson	459,720(3)	2.03%	
David McWilliams	1,577,285(4)	6.85%	
Eric Rothe	787,902(5)	3.49%	
Kenneth Hallock	755,690(6)	3.30%	
All current executive officers and directors as a group (6 persons)	25,488,301	91.52%	

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

- (1) Consists of (i) 493,780 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) 5,025,000 shares of common stock owned by Patel Family Trust 2, (v) 5,050,000 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 1,506,945 shares of common stock held by Snehal Patel which vest in 31 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 150,695 shares of common stock which vest in 31 equal monthly installments.
- (3) Excludes 215,280 shares of common stock which vest in 31 equal monthly installments.
- (4) Consists of (i) 1,121,874 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 64,585 shares of common stock which vest in 31 equal installments.
- (5) Excludes 43,060 shares of common stock which vest in 31 equal monthly installments.
- (6) Consists of (i) 6,940 shares of common stock owned by Kenneth Hallock, (ii) 437,500 shares of common stock owned by the Kenneth and Annette Hallock Revocable Trust (the "Hallock Trust"), (iii) 50,000 shares of common stock underlying shares of Series B Preferred Stock owned by the Hallock Trust, (iv) 50,000 shares of common stock underlying shares of Series C Preferred Stock owned by the Hallock Trust and (v) 211,250 shares of common stock underlying shares of Series D Preferred Stock owned by the Hallock Trust. Excludes 43,060 shares of common stock which vest in 31 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 December 31, 2019, there were 22,582,889 shares of common stock, held by 19 holders of record and 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 issued and outstanding.

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 December 31, 2019, 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.”

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 .

Stock Market Listing

We intend to apply to have our shares of common stock listed for trading on The Nasdaq Capital Market under the symbol “GLS.” 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 intend to apply 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 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. The remaining shares of our common stock outstanding after this offering will be subject to a -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, as applicable, 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 -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.

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

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

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 summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase additional shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

The representatives have 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 \$ _____, agreed to reimburse the underwriters for certain of their expenses, in an amount up to \$ _____, Authority, Inc. of the terms of this offering, as set forth in the underwriting agreement.

(excluding estimated underwriting discounts and commissions). We have also _____, incurred in connection with review by the Financial Industry Regulatory

Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for _____ 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 of all of our outstanding stock have agreed that, for a period of _____ 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 _____, (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.

_____, in its sole discretion, may release the common stock and other securities subject to the lock-up 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, _____ 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.

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 intend to apply to have our common stock listed on The Nasdaq Capital Market under the symbol "GLS."

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.

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the shares of common stock offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the shares of common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of common stock or possession or distribution of this prospectus or any other offering or publicity material relating to the shares of common stock in any country or jurisdiction (other than the U.S.) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any shares of common stock or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of shares of common stock by it will be made on the same terms.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any common stock which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any common stock under, the offers contemplated here in this prospectus will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

- it is a qualified investor as defined under the Prospectus Directive; and
- in the case of any common stock acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the common stock acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the representatives of the underwriters has been given to the offer or resale or (ii) where common stock have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such common stock to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an “offer of common stock to the public” in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any common stock to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the “FSMA”)) as received in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common stock in, from or otherwise involving the United Kingdom.

Notice to Residents of Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

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 _____.

EXPERTS

The financial statements of Greenwich LifeSciences, Inc. as of December 31, 2018 and 2017 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.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission's website at <http://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 Securities and Exchange Commission's public reference room, and 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, 2018 and 2017, 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, 2018 and 2017, 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

January 27, 2020

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2018 AND 2017

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets		
Cash	\$ 85,102	\$ 54
Total current assets	<u>85,102</u>	<u>54</u>
Acquired patents, net	23,443	27,050
Total assets	<u><u>\$ 108,545</u></u>	<u><u>\$ 27,104</u></u>
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable & accrued interest	\$ 277,556	\$ 161,146
Unreimbursed expenses	30,889	76,203
Advance from related party/shareholder	420,154	320,154
Total current liabilities	<u>728,599</u>	<u>557,503</u>
Related party payable	9,500,000	8,000,000
Total liabilities	<u><u>10,228,599</u></u>	<u><u>8,557,503</u></u>
Stockholders' deficit		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 541,991 shares issued and outstanding as of December 31, 2018 and 2017	542	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, 2018 and 2017	4,061	4,061
Series B preferred stock: 345,132 issued and outstanding as of December 31, 2018 and 2017	345	345
Series C preferred stock: 177,750 issued and outstanding as of December 31, 2018 and 2017	178	178
Series D preferred stock: 703,762 and 653,762 issued and outstanding as of December 31, 2018 and 2017, respectively	704	654
Additional paid-in capital	13,662,800	13,562,850
Accumulated deficit	(23,788,684)	(22,099,029)
Total stockholders' deficit	<u>(10,120,054)</u>	<u>(8,530,399)</u>
Total liabilities and stockholders' deficit	<u><u>\$ 108,545</u></u>	<u><u>\$ 27,104</u></u>

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Year Ended December 31,	
	2018	2017
Revenue	\$ -	\$ -
Operating expenses		
Research and development	1,270,016	1,223,051
General and administrative	419,639	350,419
Total operating expenses	1,689,655	1,573,470
Loss from operations	(1,689,655)	(1,573,470)
Net loss	\$ (1,689,655)	\$ (1,573,470)
Per share information:		
Net loss per common share, basic and diluted	\$ (3.12)	\$ (2.90)
Weighted average common shares outstanding, basic and diluted	541,991	541,991

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Common Stock		Preferred Stock		Additional	Accumulated	Total
	Shares	Par Amount	Shares	Par Amount	Paid- in Capital	Deficit	Stockholders' Deficit
Balances, December 31, 2016	541,991	\$ 542	5,327,540	\$ 5,328	\$ 13,652,760	\$ (20,525,559)	\$ (6,866,929)
Preferred Stock Repurchase	-	-	(90,000)	(90)	(89,910)	-	(90,000)
Net loss						(1,573,470)	(1,573,470)
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)

See accompanied notes to financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	Year Ended December 31,	
	2018	2017
Operating activities:		
Net loss	\$ (1,689,655)	\$ (1,573,470)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	3,607	3,607
Changes in operating assets and liabilities:		
Accounts payable	80,967	144,913
Accrued interest	35,442	16,232
Unreimbursed expenses (accrued)	(45,313)	37,871
Related party payable	1,500,000	1,250,000
Net cash used in operating activities	<u>(114,952)</u>	<u>(120,847)</u>
Investing activities:		
Financing activities:		
Proceeds/repurchase of preferred stock	100,000	(90,000)
Advance from related party/shareholder	100,000	10,154
Repayment to related party/shareholder	-	(50,000)
Net cash provided by (used in) financing activities	<u>200,000</u>	<u>(129,846)</u>
Net increase (decrease) in cash	85,048	(250,693)
Cash, beginning of period	54	250,747
Cash, end of period	<u>\$ 85,102</u>	<u>\$ 54</u>

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, 2018, the Company had cash of \$85,102. 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, 2018.

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

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, 2018 and 2017, the Company has common stock equivalents related to warrants outstanding to acquire 7,143,823 shares of the Company's common stock, 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.

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.

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 \$30,889 as of December 31, 2018 and \$76,203 as of December 31, 2017. 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. Kenneth Hallock, a director of the Company, is one of the Trustees of the Hallock Trust. In 2017, \$50,000 of Snehal Patel's outstanding loan balance was repaid and Snehal Patel loaned \$10,514 to the Company that is payable on demand, is not secured, and does not incur interest. In addition, an officer of the Company who is also a director of the Company as well as a shareholder that is affiliated with a director of the Company have loaned capital to the Company that is payable on demand, is not secured, and does not incur interest, which in the aggregate total \$420,154 as of December 31, 2018 and \$320,154 as of December 31, 2017.

Related party payables include obligations to management for services provided at various points of time in the Company's history, which total \$9.5 million as of December 31, 2018 and \$8.0 million as of December 31, 2017.

5. Income Taxes

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	596,018	556,191
Valuation allowance	(596,018)	(556,191)
Total deferred tax assets	-	-

The federal income tax rate used for 2018 and 2017 was 21%. At December 31, 2018, the Company had federal net operating loss ("NOL") carryforwards of approximately \$2.8 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, which total \$277,556 as of December 31, 2018 and \$161,146 as of December 31, 2017.

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 is adequate insurance to cover many different types of liabilities, 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

No new equity was raised in 2018 and 2017, except for the transfer of preferred stock from one custodian to another which included the final transaction for the repurchase of 90,000 shares of Series C Preferred Stock from a custodian in 2017 at the original issuance price of \$1.00 per share and 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, 2018, 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.

As of December 31, 2018, 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, 2018, 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, 2018, 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 2018 and 2017. At December 31, 2018 and 2017, 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 and 2017 was \$1.64 per share with remaining terms expiring between July 27, 2020 to June 30, 2025.

8. Subsequent Events

On July 5, 2019, the Company entered into a manufacturing purchase order for supply of GP2 for the planned Phase III clinical trial with Polypeptide Laboratories of San Diego, CA.

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 such 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, all of the \$12 million of related party payables and all of the Company’s 7,143,823 warrants were exchanged for 21,393,823 shares of the Company’s common stock leaving the Company with no related party payables and no outstanding warrants, and 415,000 shares of the Company’s common stock was issued upfront in consideration for services and 2,425,000 shares of the Company’s common stock were authorized to be issued based on various vesting schedules that start monthly vesting on October 1, 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.

In October 2019, the Kenneth Hallock and Annette Hallock Revocable Trust loaned \$200,000 to the Company and Eric Rothe loaned \$15,000 to the Company, both of which are payable on demand, are not secured, and do not incur interest.

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF SEPTEMBER 30, 2019 AND DECEMBER 31, 2018

	September 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets		
Cash	\$ 6,002	\$ 85,102
Total current assets	6,002	85,102
Acquired patents, net	20,738	23,443
Total assets	\$ 26,740	\$ 108,545
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable & accrued interest	\$ 643,247	\$ 277,556
Unreimbursed Expenses	172,164	30,889
Advance from related party/shareholder	420,154	420,154
Total current liabilities	1,235,565	728,599
Related party payable	-	9,500,000
Total liabilities	1,235,565	10,228,599
Stockholders' deficit		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,350,814 and 541,991 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	22,351	542
Preferred stock, \$0.001 par value; 6,795,000 shares authorized;		
Series A preferred stock: 4,060,896 issued and outstanding as of September 30, 2019 and December 31, 2018	4,061	4,061
Series B preferred stock: 345,132 issued and outstanding as of September 30, 2019 and December 31, 2018	345	345
Series C preferred stock: 177,750 issued and outstanding as of September 30, 2019 and December 31, 2018	178	178
Series D preferred stock: 703,762 issued and outstanding as of September 30, 2019 and December 31, 2018	704	704
Additional paid-in capital	25,640,991	13,662,800
Accumulated deficit	(26,877,455)	(23,788,684)
Total stockholders' deficit	(1,208,825)	(10,120,054)
Total liabilities and stockholders' deficit	\$ 26,740	\$ 108,545

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

	Nine Months Ended September 30,	
	2019	2018
Revenue	\$ -	\$ -
Operating expenses		
Research and development	2,347,746	108,672
General and administrative	741,025	25,112
Total operating expenses	3,088,771	133,784
Loss from operations	(3,088,771)	(133,784)
Net loss	(3,088,771)	(133,784)
Per share information:		
Net loss per common share, basic and diluted	\$ (4.97)	\$ (0.25)
Weighted average common shares outstanding, basic and diluted	621,658	541,991

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

	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 Purchase	-	-	50,000	50	99,950	-	100,000
Net loss						(133,784)	(133,784)
Balances, September 30, 2018	<u>541,991</u>	<u>\$ 542</u>	<u>5,287,540</u>	<u>\$ 5,288</u>	<u>\$ 13,662,800</u>	<u>\$ (22,232,813)</u>	<u>\$ (8,564,183)</u>
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 & common stock grant	21,808,823	21,809	-	-	11,978,191	-	12,000,000
Net loss						(3,088,771)	(3,088,771)
Balances, September 30, 2019	<u>22,350,814</u>	<u>\$ 22,351</u>	<u>5,287,540</u>	<u>\$ 5,288</u>	<u>\$ 25,640,991</u>	<u>\$ (26,877,455)</u>	<u>\$ (1,208,825)</u>

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	\$ (3,088,771)	\$ (133,784)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	2,705	2,705
Changes in operating assets and liabilities:		
Accounts payable	323,092	80,967
Accrued interest	42,599	-
Unreimbursed expenses (accrued)	141,275	(14,840)
Related party payable	2,500,000	-
Net cash used in operating activities	(79,100)	(64,952)
Investing activities:		
Financing activities:		
Proceeds from sale of preferred stock	-	100,000
Advance from related party/shareholder	-	100,000
Net cash provided by (used in) financing activities	-	200,000
Net increase (decrease) in cash	(79,100)	135,048
Cash, beginning of period	85,102	54
Cash, end of period	\$ 6,002	\$ 135,102
Non-cash investing and financing activities:		
Common stock to settle related party payable	12,000,000	

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 September 30, 2019, the Company had cash of \$6,002. 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 the Company’s Form S-1.

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, 2018 and 2017 as reported in this Form S-1 have been omitted.

Basic and Diluted Loss per Share

As of September 30, 2019, the Company does not have common stock equivalents related to options or warrants. As of September 30, 2018, the Company has common stock equivalents related to warrants outstanding to acquire 7,143,823 shares of the Company’s common stock.

As of September 30, 2019 and 2018, 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.

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

	Nine Months Ended September 30,	
	2019	2018
Basic and diluted net loss per share calculation:		
Net loss, basic	(3,088,771)	(133,784)
Change in fair value of warrants	-	-
Net loss, diluted	(3,088,771)	(133,784)
Weighted average common shares outstanding, basic and diluted	621,658	541,991
Net loss per common share, basic and diluted	\$ (4.97)	\$ (0.25)

4. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total \$172,164 as of September 30, 2019 and \$30,889 as of December 31, 2018. In 2018, the Kenneth Hallock and Annette Hallock Revocable Trust loaned \$100,000 to the Company that is payable on demand, is not secured, and does not incur interest. Kenneth Hallock, a director of the Company, is one of the Trustees of the Hallock Trust. In addition an officer of the Company who is also a director of the Company as well as a shareholder that is affiliated with a director of the Company have loaned capital to the Company that is payable on demand, is not secured, and does not incur interest, which in the aggregate total \$420,154 as of September 30, 2019 and December 31, 2018.

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. 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 \$643,247 as of September 30, 2019 and \$277,556 as of December 31, 2018.

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 is adequate insurance to cover many different types of liabilities, the Company's future insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, could have a material adverse effect on our results of operations or financial position.

6. Stockholders' Deficit

On September 30, 2019, the board of directors (the "Board") and stockholders of the Company adopted the Greenwich LifeSciences, Inc. 2019 Equity Incentive Plan setting aside and reserving 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 no value based on various vesting schedules that start monthly vesting on October 1, 2019. As of September 30, 2019, none of the 2,425,000 shares of the common stock grant had vested and all of these shares remain unvested.

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 2018, except for the transfer of preferred stock from one custodian to another which was 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. No new equity was raised in 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 September 30, 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 September 30, 2019
7,143,823	(7,143,823)	-

7. Subsequent Events

In October 2019, the Kenneth Hallock and Annette Hallock Revocable Trust loaned \$200,000 to the Company and Eric Rothe, a director, 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.

Shares



Common Stock

Prospectus

, 2020

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	\$ *
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 General Corporation Law of the State of Delaware (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.

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement will provide, among other things, for indemnification to the fullest extent permitted by law and our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements will 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 under applicable law and our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws.

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 a consultant an aggregate of 415,000 shares of the Company's common stock as consideration for services.

From October 1, 2019 to January 1, 2020, the Company issued officers, directors and a consultant an aggregate of 276,100 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.

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

Item 16. Exhibits and Financial Statement Schedules

EXHIBIT INDEX

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

* 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 Sugar Land, State of Texas, on the _____ day of _____, 2020.

GREENWICH LIFESCIENCES, INC.

By: _____

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