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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended

December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-34375

PLUS THERAPEUTICS, INC.

(previously known as Cytori Therapeutics, Inc.)
(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**33-0827593**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4200 MARATHON BLVD. SUITE 200, AUSTIN,TX	**78756**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (737) 255-7194

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	PSTV	Nasdaq Capital Market

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

None.

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was $5.4 million based on the closing sales price of the registrant's common stock on June 28, 2019 as reported on the Nasdaq Capital Market, of $12.11 per share.

As of March 20, 2020, there were 3,880,588 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements about our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; the Company's strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; the potential size of the market for our products; our research and development efforts; our IP strategy; competition; future development and/or expansion of our products and therapies in our markets; our pipeline; our ability to generate product or development revenues and the sources of such revenues; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the "Liquidity and Capital Resources" section of this report, including our potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; our ability to transfer the drug product manufacture for ATI 1123 to a contract drug manufacturing organization; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. Our actual results will likely differ, perhaps materially, from those anticipated in these forward-looking statements as a result of various factors, including: the early stage of our product candidates and therapies, the results of our research and development activities, including uncertainties relating to the clinical trials of our product candidates and therapies; our liquidity and capital resources and our ability to raise additional cash, the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, market conditions, product performance, potential litigation, and competition within the regenerative medicine field, to name a few. The forward-looking statements included in this report are subject to a number of additional material risks and uncertainties, including but not limited to the risks described under the "Risk Factors" in Item 1A of Part I below, which we encourage you to read carefully.

We encourage you to read the risks described under "Risk Factors" carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance.

PART I

Item 1. Business

References to "Plus," the "Company," "we," "us" and "our" refer to Plus Therapeutics, Inc. and its consolidated subsidiaries. References to "Notes" refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

General

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the discovery, development, and delivery of complex and innovative treatments for patients battling cancer and rare diseases. Our objective is to build a profitable and growing pharmaceutical company. To meet this objective, we are focused on developing our Nanomedicine platform which holds promise for treating millions of patients and represents significant potential for increasing shareholder value.

We are a company with expertise in both drug and medical device development, manufacturing, and commercial operations. We also have a specific core competency in drug reformulation using nanoparticles. Our proprietary Nanomedicine platform provides enhanced delivery options and improved pharamacokinetics for a variety of drugs. Nanoparticle drug formulation has undergone significant technical and commercial evolution since it was first developed. Our platform facilitates new delivery approaches and/or formulations for a variety of clinically proven therapies, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers.

We plan to leverage our Nanomedicine platform and expertise using a simple model that enables us to address unmet needs or underserved conditions while managing risks and minimizing development costs through: (1) the mapping of the current and anticipated market landscape to clearly understand the clinical and commercial opportunities and defining nanotechnology options, (2) the redesign of known, safe and effective active pharmaceutical ingredients with new nanotechnology, (3) the manufacture-to-scale of reformulated drugs along with critical non-clinical (i.e. bench, animal) analyses, (4) evaluation of early-stage clinical utility with a focus on proving safety and defining efficacy over the current standard of care, and (5) potential global partnering of the innovative treatment for late-stage clinical trials, regulatory approval, and commercial launch

Recent Developments

Sale of the UK Subsidiary and Certain Assets

On March 30, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the "Lorem Purchase Agreement") with Lorem Vascular Pte. Ltd. ("Lorem"), pursuant to which, among other things, Lorem agreed to purchase the Company's UK subsidiary, Cytori Ltd., and the Company's Cell Therapy assets, excluding such assets used in Japan or relating to the Company's contract with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA"). Both the Company and Lorem made customary representations, warranties and covenants in the Lorem Purchase Agreement. The transaction was completed on April 24, 2019 and the Company received $4.0 million of cash proceeds, of which $1.7 million was used to pay down principal, interest and fees under the Loan and Security Agreement, dated May 29, 2015 (the "Loan and Security Agreement"), as amended, with Oxford Finance, LLC ("Oxford").

Sale of the Japanese Subsidiary and Certain Assets

On April 19, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the "Shirahama Purchase Agreement") with Seijirō Shirahama, pursuant to which, among other things, Mr. Shirahama agreed to purchase the Company's Japanese subsidiary, Cytori Therapeutics, K.K., and substantially all of the Company's Cell Therapy assets used in Japan. Both the Company and Mr. Shirahama made customary representations, warranties and covenants in the Shirahama Purchase Agreement. The transaction was completed on April 25, 2019 and the Company received $3.0 million of cash proceeds, of which $1.4 million was used to pay down principal, interest and fees under the Loan and Security Agreement.

Name Change

On July 29, 2019, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended (the "July 2019 Amendment"), with the Secretary of State of the State of Delaware to effect a change of the Company's corporate name from "Cytori Therapeutics, Inc." to "Plus Therapeutics, Inc." In addition, the Company moved its headquarter from California to Austin, Texas.

Reverse Stock Split

On August 5, 2019, the Company filed a Certificate of Amendment (the "August 2019 Amendment") to its Amended and Restated Certificate of Incorporation (the "Amendment"), as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-fifty (1:50) reverse stock split (the "August 2019 Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value or authorized number of common stock. Upon effectiveness, each 50 shares of issued and outstanding common stock were converted into one newly issued and outstanding share of common stock. The Company's 5,000,000 shares of authorized preferred stock were not affected by the August 2019 Reverse Stock Split. Any fractional shares of common stock that would have otherwise resulted from the August 2019 Reverse Stock Split were rounded up to the nearest whole share. Outstanding equity awards and the shares available for future grant under the Company's 2014 Amended and Restated Equity Incentive Plan and 2015 New Employee Incentive Plan were proportionately reduced (rounded down to the nearest whole share), and the exercise prices of outstanding equity awards were proportionately increased (rounded up to the nearest whole cent) to give effect to the August 2019 Reverse Stock Split.

BARDA Reimbursement

In September 2019, the Company finalized the indirect cost rate under the BARDA Agreement for indirect costs incurred during the years 2012 through 2019, which resulted in approximately $4.6 million reimbursement revenue recognized during the year ended December 31, 2019.

September 2019 Offering

In September 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the "Representative"), as representative of the underwriters (the "Underwriters"), pursuant to which the Company sold the Underwriters in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value $0.001 per share, of the Company and one Series U warrant to purchase one share of common stock, and (ii) 2,711,000 Class B Units, each consisting of one pre-funded Series V Warrant to purchase one share of common stock and one Series U Warrant to purchase one share of common stock at a public offering price of $5.00 per Class A Unit and $4.9999 per Class B Unit. In addition, the Company granted the Underwriters Series U warrants to purchase up to 450,000 shares of common stock. The Company also issued to the Representative warrants (in the form of the Series U warrants) to purchase 75,000 shares of common stock with an exercise price of $6.25 per share of common stock. The Series V warrants were fully exercised as of December 31, 2019.

The Series U warrants became exercisable upon issuance and will expire on the five-year anniversary of the date of issuance. The Series U warrants may not be exercised by the holder to the extent that, after giving effect to an exercise, the holder, together with its affiliates and certain related parties, would beneficially own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the common stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon notice to the Company, provided that such limitation cannot exceed 9.99%, and provided that any increase in the beneficial ownership limitation will not be effective until 61 days following notice of such increase from the holder to the Company). The Company does not intend to apply for listing of the Series U warrants on the Nasdaq Capital Market, any other securities exchange or any other trading system.

The net proceeds to the Company from the offering was approximately $13.2 million, after deducting underwriting discounts and commissions and other estimated offering expenses and excluding the exercise of any warrants and the Underwriters' option to purchase additional securities. The net proceeds were used for working capital, payment of interest on its debt and general corporate purposes, which may include research and development of its oncology product pipeline, preclinical and clinical trials and studies, regulatory submissions, expansion of its sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures.

Pipeline

Our lead product candidate, DocePLUS, is a protein-stabilized PEGylated liposomal formulation of docetaxel, for which the process of preparation is patented. The active pharmaceutical ingredient, docetaxel, was approved by the U.S. Food and Drug Administration (the "FDA") in 1999 and commonly used for treating cancers of the breast, head, neck, stomach, prostate, and lung.

In non-clinical studies utilizing mouse tumor models (lung, prostate, pancreatic, and mesothelioma), DocePLUS exhibited anti-tumor activity and was well-tolerated.

A Phase 1 clinical trial was conducted under an approved FDA Investigational New Drug Application to examine the safety, pharmacokinetics, and pharmacodynamics of DocePLUS in 29 patients with solid tumors. The completed and published trial demonstrated that DocePLUS has an acceptable tolerability, a favorable pharmacokinetic profile, as well as promising anti-tumor activity that we believe warrants further exploration in larger Phase 2 trials.

The development targets for DocePLUS are potentially broad, however our initial focus is to develop a new second-line treatment option for small cell lung cancer. Single-agent chemotherapy with IV topotecan is currently the only FDA approved drug for platinum-sensitive patients who relapse at least 60 days after initiation of first-line treatment. Intravenously administered topotecan demonstrates activity in this population, however, overall response rate (24%), response duration (3.3 months), time to progression (3.1 months), and overall survival (5.8 months) were not statistically improved over CAV (cyclophosphamide, doxorubicin, and vincristine) treatment in a randomized comparative trial of patients with recurrent or progressive small cell lung cancer. Patients receive 1.5 mg/m2 IV infusion of topotecan over 30 minutes daily for 5 consecutive days, starting on Day 1 of a 21-day cycle. We believe there is a clinical need for more effective and convenient treatment options for patients with small cell lung cancer with platinum-sensitive disease who relapsed.

Besides potential safety and efficacy benefits of DocePLUS, the dosing regimen for DocePLUS in small cell lung cancer patients will be only a 60 minute infusion on a single day, starting on Day 1 of a 21-day cycle. This approach will reduce the patient's number of visits to an infusion center from 5 (IV topotecan) to 1 in a given 21-day cycle. Overall, DocePLUS is intended to provide an effective, safe, and convenient therapeutic option for small cell lung cancer patients, thereby improving the quality of life for this population.

Recent key events associated with DocePLUS development include:

- In September 2018, the FDA granted DocePLUS an orphan drug designation for the treatment of small cell lung cancer.
- In the first half of 2019, we collaborated with an experienced global market evaluation firm in mapping the current and anticipated landscape, performing primary market research with U.S. medical oncologists and payers, suggesting small cell lung cancer as well as several other oncology targets represent compelling future disease targets with significant patient-benefit and revenue potential.
- In July 2019, we announced receipt of FDA feedback including confirmation that a 505(b)(2) application appears to be an acceptable regulatory path with docetaxel injection as a potentially acceptable listed drug. Furthermore, the FDA agreed that the completed nonclinical studies are sufficient to support the initiation of a clinical trial of DocePLUS in patients with platinum-sensitive small cell lung cancer who have progressed at least 60 days after initiation of first-line therapy.
- In the second half of 2019, we completed process characterization studies in support of the Chemistry, Manufacturing and Controls (CMC) section of IND submission in the San Antonio, TX facility. Requests for Proposal were circulated to key Contract Drug Manufacturing Organization (CDMO) candidates for the scale, manufacture and sterile fill of the clinical drug product. A contract test facility was identified and contracted for Analytical Method Development. Method development was initiated for in-process and release testing of clinical drug product.

Our next step is to conduct a Phase 2 clinical trial in small cell lung cancer under our existing, approved Investigation New Drug application. We expect the goal of this trial will be to assess safety and investigate efficacy signals in patients with platinum-sensitive small cell lung cancer who have progressed. We also expect the trial will also support the statistical powering or a pivotal trial for the same indication.

We have also completed significant development work on DoxoPLUS, a generic version of Janssen's DOXIL®/CAELYX®, a PEGylated liposomal encapsulated doxorubicin for the treatment of breast and ovarian cancer, multiple myeloma, and Kaposi's sarcoma. PEGylated liposomal encapsulated doxorubicin is a heavily relied upon chemotherapeutic used globally for treating many types of cancer. We believe that data from a 38-patient European study of DoxoPLUS has met the statistical criteria for bioequivalence to CAELYX®, the current reference listed drug in Europe. We believe that these bioequivalence data for DoxoPLUS can serve as a basis for a Marketing Authorization Application to be submitted to EMA. The market size for PEGylated liposomal encapsulated doxorubicin in Europe is approximately $130 million. Our plan is to partner or divest DoxoPLUS and we are currently in discussions with third parties. We do not currently plan to expend any more of our own funds to advance DoxoPLUS.

We intend to build our pipeline beyond DoxoPLUS and DocePLUS through a combination of internal development and the in-licensing and/or acquiring drugs for niche and orphan markets, primarily in oncology, that address significant unmet or substantially underserved medical needs and that represent global revenue opportunities greater than $250 million. We intend to focus our pipeline on products that maximize our in-house expertise in nanoparticle drug design and complex formulation and leverage accelerated regulatory pathways by the FDA

While we are continually evaluating new potential product development candidates, we do not currently have any active product candidates other than DocePLUS.

Sales, Marketing and Service

For DocePLUS, we are actively seeking regional and global partnerships with leading pharmaceutical companies for the development and commercialization of the asset for a variety of other indications. For DoxoPLUS, we are looking to partner or divest the asset to a leading international pharmaceutical company with a successful track record with complex generic drugs.

Manufacturing

We have a dedicated nanoparticle research & development as well as commercial scale manufacturing facility located in San Antonio, Texas. The facility and processes are designed to comply with current good manufacturing practices ("cGMP") per FDA and EMA regulations to manufacture drug candidates for clinical, research, development and commercial use. Upon approval of our drug candidates, our manufacturing capabilities will include validated manufacturing processes for drug product as well as a quality assurance product release process with the ability to ultimately scale-up the process to meet increasing market demands. We believe our strategic investments in the analytical and manufacturing capabilities, including personnel from drug discovery through drug development, will allow us to advance our product candidates more quickly. Expertise gained in manufacturing both of our drug products may be applied to other formulations in the future, further leveraging our capabilities. Our San Antonio facility enables us to produce drug substances in a cost-effective manner while retaining control over the process and timing. As needed, the use of a qualified Contract Drug Manufacturing Organization (CDMO) may be utilized to perform various manufacturing processes as we deem appropriate to meet our operational objectives.

Our current principal suppliers for our Nanomedicine business are Eurofins BioPharma Product Testing Columbia, which provides analytical method development and product release testing for our drug candidates, ScinoPharm Taiwan. Ltd., which supplies Docetaxel, our active pharmaceutical ingredient ("API"), as well as Lipoid, LLC and Dishman Netherlands, B.V., which supply us with other raw materials used in the manufacture of our Nanomedicine product candidates. Each of these suppliers is currently a sole source supplier.

Competition

We compete primarily on the basis of the safety and efficacy of our therapies across a broad range of clinical indications to address significant unmet medical and market needs, supported by our brand name, pricing, products, published clinical data, regulatory approvals, and reimbursement. We believe that our continued success depends on our ability to:

- develop and innovate our product and technology platforms;
- initiate new and advance existing clinical development programs;
- secure and maintain regulatory agency approvals;
- build and expand our commercial footprint;
- produce high quality products per our specifications and in line with customer expectations;
- achieve improved economies of scale and scope;

- generate and protect intellectual property;
- hire and retain key talent; and
- successfully execute acquisition, licensing, and partnership activities.

DoxoPLUS, our generic pegylated liposomal encapsulated doxorubicin product candidate, is expected to face competition from both branded and generic nanomedicine products for the treatment of breast cancer (BC), ovarian cancer (OC), multiple myeloma (MM), and/or Kaposi's Sarcoma (KS) in all geographies. New nanoparticle-doxorubicin monotherapies and drug combination therapies represent next generation approaches intended to be safer and more effective than today's branded and generic pegylated liposomal doxorubicin (PLD). The table below provides information about certain potential competitors to DoxoPLUS and information related to their relevant product.

U.S.				
Company	**Product**	**Formulation**	**Stage**	**Indications**
JNJ Janssen	DOXIL	PLD	Commercial	BC, OC, MM, KS
JNJ Janssen	Authorized Generic	PLD	Commercial	BC, OC, MM, KS
Sun	Lipodox	PLD	Commercial	BC, OC, MM, KS
Dr. Reddy's	Doxorubicin HCl Liposome	PLD	Commercial	BC, OC, MM, KS
Ipsen	Doxorubicin Liposome	PLD	ANDA Submitted	BC, OC, MM, KS
Fudan Zhangjiang	Libod	PLD	BE Study vs Sun Lipodox	OC
Tolmar	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Panacea Biotech	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Emcure	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Cadila	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Cipla	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Aurobindo	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Intas	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Mylan	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Ayana	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Celerity	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Watson	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC

Europe				
Company	**Product**	**Formulation**	**Stage**	**Indications**
JNJ Janssen	CAELYX	PLD	Commercial	BC, OC, KS
Teva	Myocet	Non-PLD	Commercial	Breast (with cyclophosphamide)
Dr. Reddy's	Doxorubicin HCl Liposome	PLD	MAA Submitted	BC, OC
Sun Pharma	Lipodox	PLD	BE Study vs Janssen CAELYX	BC, OC
Teva	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC, OC
Emcure	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC, OC
Celerity	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC
Intas	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	OC
Tolmar	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC, OC

Rest of World				
Country	**Company**	**Product**	**Formulation**	**Stage**
China	Fudan Zhangjiang	Libod	PLD	Commercial
China	CSPC	Duomeisu	PLD	Commercial
China	Changzhou Jinyuan	Lixing	PLD	Commercial

Our DocePLUS product candidate is expected to face competition from both Sanofi's Taxotere, which is approved for 11 indications and available in 90 countries with a majority of sales from China, Japan, Korea, and Taiwan, and generic docetaxel which is available from major suppliers in the U.S., Europe and Japan including, but not limited to, Accord, Actavis, Dr. Reddy's Labs, GLS Pharma, Hospira, Sun Pharma, Teva, and Winthrop. Further competition may result from advances made by companies currently developing nanoparticle-docetaxel products including, but not limited to, Adocia, Athenex, Bind Therapeutics, Bluelink Pharmaceuticals, Changzhou Jinyuan, Cristal Therapeutics, Intas, LIDDS, Modra, NanOlogy, Oasmia, and Starpharma.

Further, DocePLUS may face direct competition in the future with drugs currently being developed and registered for the treatment of small cell lung cancer including, but not limited to:

Drug	Phase 1	Phase 2	Phase 3	Registration	Approved
Merck pembrolizumab	X	X			
AstraZeneca olaparib + temozolomide	X	X			
AstraZeneca tremelimumab + durvalumab ± radiation	X	X			
Millennium alisertib + paclitaxel	X	X			
BMS gemcitabine + nivolumab	X	X			
United Therapeutics dinutuximab + irinotecan	X	X	X		
Ipsen liposomal irinotecan	X	X	X		
PharmaMar lurbinectedin + doxorubicin	X	X	X		
PharmaMar lurbinectedin	X	X	X	X	
Novartis topotecan	X	X	X	X	X

Intellectual Property

Our success depends in large part on our ability to protect our proprietary technology, and to operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities.

We cannot assure that any of our pending patent applications will be issued, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure that others will not independently develop similar products, duplicate any of our products or design around our patents. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. For many of our pending applications, patent interference proceedings may be instituted with the U.S. Patent and Trademark Office (the “USPTO”), when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO’s decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. Third parties can file post-grant proceedings in the USPTO, seeking to have issued patent invalidated, within nine months of issuance. This means that patents undergoing post-grant proceedings may be lost, or some or all claims may require amendment or cancellation, if the outcome of the proceedings is unfavorable to us. Post-grant proceedings are complex and could result in a reduction or loss of patent rights. The institution of post-grant proceedings against our patents could also result in significant expenses.

Patent law outside the United States is uncertain and, in many countries, is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors’ patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. We currently have pending patent applications or issued patents in the United States, Europe, and Canada, among others.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We cannot assure you that others will not independently develop or otherwise acquire substantially equivalent techniques, somehow gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we can ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Government Regulation

Our nanoparticle oncology drug products must receive regulatory approvals from the EMA and the FDA and from other applicable governments prior to their sale.

Our current and future nanoparticle oncology drugs are, or will be, subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution, and promotion of oncology drugs. Included among these regulations are drug approval requirements and the current Good Manufacturing Practices, cGMP. Other statutory and regulatory requirements govern, among other things, cGMP inspection, prohibitions against misbranding and adulteration, labeling and post-market reporting.

Our nanoparticle oncology drugs must also comply with the government regulations of each individual country in which the products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. International government regulations vary from country to country and region to region. For instance, our DocePLUS drug candidate relies on an expedited approval process referred to as bioequivalence (“BE”) approved under an Abbreviated New Drug Application (“ANDA”). ANDA and BE products require a reference drug, reference standard (“RS”), and/or reference listed drug (or “RLD”), to with which to show equivalence. The reference drug may not be the same in all territories or countries, which could require different and unique BE clinical studies for some territories. Furthermore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Additionally, government regulations can change with little to no notice and may result in the elimination of the BE regulatory pathway in some regions, creating increased regulatory burden.

Worldwide, the regulatory process can be lengthy, expensive, and uncertain with no guarantee of approval. Before any new drugs may be introduced to the U.S. market, the manufacturer generally must obtain FDA approval through either ANDA process for generic drugs off-patent that allow for bioequivalence to an existing reference listed drug, or the lengthier new drug approval (“NDA”) process, which typically requires multiple successful Phase III clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. Approval of an ANDA could take four or more years from the time the development process is initiated due to the requirement for clinical trials. NDA drugs could take significantly longer due to the additional preclinical requirements along with the typical requirement for two successful Phase III clinical trials.

Our DoxoPLUS drug candidate is eligible for the ANDA regulatory pathway in the U.S., while our DoxoPLUS drug candidate may be subject to the significantly lengthier 505(b)(1) or 505(b)(2) NDA process. Changes to the RS and RLD for drugs eligible for the ANDA process can result in significant delays in the regulatory process as BE clinical studies may need to be repeated for regions / countries that no longer recognize the RS or RLD utilized in BE clinical studies. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals, refusals to approve new applications or notifications, and criminal prosecution.

Drugs are also subject to post-market reporting requirements for deaths or serious injuries when the drug may have caused or contributed to the death or serious injury, or serious adverse events. If safety or effectiveness problems occur after the drug reaches the market, the FDA may take steps to prevent or limit further marketing of the drug. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of drugs for indications or uses that have not been approved by the FDA.

We must comply with extensive regulations from foreign jurisdictions regarding safety, manufacturing processes and quality. These regulations, including the requirements for marketing and authorization, may differ from the FDA regulatory scheme in the United States.

Employees

As of March 20, 2020, we had 12 full-time employees. Of these full-time employees, five were engaged in research and development, one was engaged in sales and marketing and six were engaged in management, finance and administration. From time to time, we also employ independent contractors to support our operations. Our employees are not represented by any collective bargaining agreements and we have never experienced an organized work stoppage.

Corporate Information

We were initially formed as a California general partnership in July 1996 and incorporated in the State of Delaware in May 1997. We were formerly known as Cytori Therapeutics, Inc., before that as MacroPore Biosurgery, Inc. and before that as MacroPore, Inc. Our corporate offices are located at 4200 Marathon Blvd., Suite 200, Austin, TX. Our telephone number is (737) 255-7194. We maintain a website at www.plustherapeutics.com.

Item 1A. Risk Factors

The risk factors described below, as well as statements described elsewhere in this Annual Report on Form 10-K, including our audited Consolidated Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Conditions and Results of Operations", or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations.

Risks Related to our Financial Position and Capital Requirements

We have incurred losses since inception, we expect to incur significant net losses in the foreseeable future and we may never become profitable.

We generated negative cash flows from operations and have incurred net operating losses each year since we started business. For the year ended December 31, 2019, we incurred net losses of $10.9 million and our net cash used in operating activities was $5.9 million. As of December 31, 2019, our accumulated deficit was $425.3 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year. As our focus on development of Nanomedicine and the development of therapeutic applications has increased, losses have resulted primarily from expenses associated with research and development and clinical trial-related activities, as well as general and administrative expenses. While we have implemented and continue to implement cost reduction measures where possible, we nonetheless expect to continue operating in a loss position on a consolidated basis and expect that recurring operating expenses will be at higher levels for the year ended December 31, 2020 as we prepare for and perform clinical trial and other development activities for our Nanomedicine product candidates.

Our ability to generate sufficient revenues from any of our products, product candidates or technologies to achieve profitability will depend on a number of factors including, but not limited to:

- our ability to manufacture, test and validate our product candidates in compliance with applicable laws and as required for submission to applicable regulatory bodies, including manufacturing, testing and validation of our DocePLUS and DoxoPLUS product candidates;
- our or our partners' ability to successfully complete clinical trials of our product candidates;
- our ability to obtain necessary regulatory approvals for our product candidates;
- our or our partners' ability to negotiate and receive favorable reimbursement for our product candidates, including for our product candidates that have been granted or may be granted orphan drug status or otherwise command currently anticipated pricing levels;
- our ability to negotiate favorable arrangements with third parties to help finance the development of, and market and distribute, our products and product candidates; and
- the degree to which our approved products are accepted in the marketplace.

Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not generate significant sales from any of our product candidates that may receive regulatory approval, there would be a material adverse effect on our business, results of operations, financial condition and prospects which could result in our inability to continue operations.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business.

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to our development programs, and any delays in, adverse events and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements at the time;
- costs associated with operating at our San Antonio, Texas facility;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;
- the level of our sales and marketing expenses;
- competing technological and market developments; and
- our ability to introduce and sell new products.

We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. Our financing plans include pursuing additional cash through the use of debt and/or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing and sales of assets and equity. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of its clinical development efforts.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. To obtain additional capital, we may pursue debt and/or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets or debt or equity securities. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and reimbursement efforts, or curtailment or cessation of operations.

Failure to raise capital as and when needed, on favorable terms or at all, would have a significant negative impact on our financial condition and our ability to develop our product candidates.

Our level of indebtedness, and covenant restrictions under such indebtedness, could adversely affect our operations and liquidity.

Under the Loan and Security Agreement, Oxford made a term loan to us in an aggregate principal amount of $17.7 million (the “Term Loan”) subject to the terms and conditions set forth therein. The outstanding principal balance of the Term Loan was $11.1 million as of December 31, 2019.

The Term Loan accrues interest at a floating rate equal to the three-month LIBOR rate (with a floor of 1.00%) plus 7.95% per annum. On March 29, 2020, we and Oxford amended the Loan and Security Agreement to extend the interest-only period. Beginning May 1, 2021, we will be required to make payments of principal and accrued interest in equal monthly installments to amortize the Term Loan through June 1, 2024, the new maturity date.

As security for our obligations under the Loan and Security Agreement, we granted a security interest in substantially all of our existing and after-acquired assets, excluding our intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement. If we are unable to discharge these obligations, Oxford could foreclose on these assets, which would, at a minimum, have a severe material adverse effect on our ability to operate our business.

Our indebtedness to Oxford could adversely affect our operations and liquidity, by, among other things:

- causing us to use a larger portion of our cash flow to fund interest and principal payments, reducing the availability of cash to fund working capital and capital expenditures and other business activities;
- making it more difficult for us to take advantage of significant business opportunities, such as acquisition opportunities, and to react to changes in market or industry conditions; and
- limiting our ability to borrow additional monies in the future to fund working capital and capital expenditures and for other general corporate purposes.

The Loan and Security Agreement, as amended, requires us to maintain at least $2.0 million in unrestricted cash and/or cash equivalents and includes certain reporting and other covenants, that, among other things, restrict our ability to (i) dispose of assets, (ii) change the business we conduct, (iii) make acquisitions, (iv) engage in mergers or consolidations, (v) incur additional indebtedness, (vi) create liens on assets, (vii) maintain any collateral account, (viii) pay dividends, (ix) make investments, loans or advances, (x) engage in certain transactions with affiliates, and (xi) prepay certain other indebtedness or amend other financing arrangements. If we fail to comply with any of these covenants or restrictions, such failure may result in an event of default, which if not cured or waived, could result in Oxford causing the outstanding loan amount to become immediately due and payable. If the maturity of our indebtedness is accelerated, we may not have, or be able to timely procure, sufficient cash resources to satisfy our debt obligations, and such acceleration would adversely affect our business and financial condition.

The report of our independent registered public accounting firm contains an emphasis paragraph regarding the substantial doubt about our ability to continue as a "going concern."

The audit report of our independent registered public accounting firm covering the December 31, 2019 consolidated financial statements contains an explanatory paragraph that states that our recurring losses from operations, liquidity position, and debt service requirements raises substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. To date, our operating losses have been funded primarily from outside sources of invested capital and gross profits. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future operations. However, no assurance can be given that additional capital will be available when required or on terms acceptable to us. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and reimbursement efforts, or the curtailment or cessation of operations. We also cannot give assurance that we will achieve sufficient revenues in the future to achieve profitability and cash flow positive operations to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause third parties to choose not to deal with us due to concerns about our ability to meet our contractual obligations, which could have a material adverse effect on our business.

We may not be able to access the full amounts available under the Lincoln Park Purchase Agreement, which could prevent us from accessing the capital we need to continue our operations, which could have an adverse effect on our business.

In September 2018, we entered into a Purchase Agreement (the "Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which we may direct Lincoln Park to purchase up to $5.0 million in shares of our common stock from time to time over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. Thereafter, on any trading day selected by us, we may sell shares of common stock to Lincoln Park in amounts up to 5,000 shares per regular sale (such purchases, Regular Purchases) up to the aggregate commitment of $5.0 million. The amount we may sell to Lincoln Park under a single Regular Purchase may increase under certain circumstances as described in the Purchase Agreement but in no event will the amount of a single Regular Purchase exceed $1.0 million. The purchase price of shares of common stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. We may also direct Lincoln Park to purchase other amounts as accelerated purchases or additional accelerated purchases if the closing sale price of the common stock is not below the threshold prices as set forth in the Purchase Agreement. There are no trading volume requirements or restrictions under the Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for common stock under a Regular Purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day our closing price is less than the floor price as set forth in the Purchase Agreement.

Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $5.0 million over the term of the Lincoln Park Purchase Agreement. For example, under the rules of the Nasdaq Capital Market, we may be restricted in our ability to issue more than 19.99% of our outstanding shares of common stock (which is approximately 775,729 shares based on 3,880,588 shares outstanding as of March 20, 2020) unless we obtain stockholder approval or we obtain an exception pursuant to the rules of the Nasdaq Capital Market to issue more than 19.99%. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 4.99% of the then outstanding shares of our common stock. Our inability to access a portion or the full amount available under the Lincoln Park Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the resale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Depending on market liquidity at the time, sales of shares under the Lincoln Park Purchase Agreement may cause the trading price of our common stock to fall. We generally have the right to control the timing and amount of any sales of our shares under the Lincoln Park Purchase Agreement. Whether or not we make sales of our common stock, if any, under the Lincoln Park Purchase Agreement will depend upon market conditions and other factors to be determined by us. Lincoln Park may resell all, some or none of the shares it purchases from us under this agreement. Sales of our common stock under the Lincoln Park Purchase Agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock under the Lincoln Park Purchase Agreement, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our budgeted expense levels are based in part on our expectations concerning future research and development activities. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events. Accordingly, unexpected events could have an immediate and material impact on our business and financial condition.

Our operating results have been and will likely continue to be volatile.

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech, pharmaceutical and medical device fields. From time to time, we have tried to update our investors' expectations as to our operating results by periodically announcing financial guidance. However, we have in the past been forced to revise or withdraw such guidance due to lack of visibility and predictability of product demand. If we revise or withdraw guidance, it could materially harm our reputation and the market's perception of us, and could cause our stock price to decline.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We do not expect to make profits in the near future. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income and taxes may be limited. We may have experienced, or may in the future experience, "ownership changes" as a result of shifts in stock ownership. Any such ownership changes could limit our ability to use net operating loss carryforwards and other pre-change tax attributes. Furthermore, under 2017 U.S. tax legislation, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond may be used to offset only 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Risks Related to Our Business and Industry

Our future success is in large part dependent upon our ability to successfully integrate and develop our Nanomedicine platform and commercialize DoxoPLUS and DocePLUS and any failure to do so could significantly harm our business and prospects.

Our ability to successfully integrate, develop and commercialize DoxoPLUS and DocePLUS is subject to a number of risks, including the following:

- we do not have substantive drug development, manufacturing, and commercialization experience, and thus we may be required to hire and rely on significant numbers of scientific, quality, regulatory and other technical personnel with the experience and expertise necessary to develop, manufacture, and commercialize our Plus Therapeutics Nanomedicine product candidates. We may be unable to identify, hire and retain personnel with the requisite experience to conduct the operations necessary to obtain regulatory approval and commercialize our DoxoPLUS and DocePLUS product candidates, in which case our business would be materially harmed;
- we intend to find a commercialization partner to share or assume responsibility for marketing, sales, and distribution activities and related costs and expenses for our DocePLUS product candidate. There can be no assurance that we would obtain sufficient capital to fund the development, manufacturing, and commercialization of our Nanomedicine program ourselves, or if we do obtain such capital, that our development, manufacturing, and commercialization efforts would be successful;

- conduct of this acquired business will require significant capital, and to the extent that we incur unanticipated expenses in our business, are unable to timely obtain sufficient additional capital on terms acceptable to us (or at all) to fund this business, our ability to develop our DocePLUS product candidate could be materially and adversely impacted;
- we have discontinued development activities for DoxoPLUS and are actively seeking to monetize this asset. New competitive products become commercially available before we launch DocePLUS; and
- we are not experienced in acquiring and integrating new businesses.

If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.

A key part of our business strategy is to leverage strategic partnerships/collaborations to commercialize our product candidates. We do not have the financial, human or other resources necessary to develop, commercialize, launch or sell our therapeutic offerings in all of the geographies that we are targeting, and thus it is important that we identify and partner with third parties who possess the necessary resources to bring our products to market. We expect that any such partners will provide regulatory and reimbursement/pricing expertise, sales and marketing resources, and other expertise and resources vital to the success of our product offerings in their territories. We further expect, but cannot guarantee, that any such partnering arrangements will include upfront cash payments to us in return for the rights to develop, manufacture, and/or sell our products in specified territories, as well as downstream revenues in the form of milestone payments and royalties.

Our current business strategy is high-risk.

Our current business strategy is to aggressively develop our Nanomedicine platforms, while simultaneously controlling expenses, which is a high-risk strategy for a number of reasons including the following:

- we do not have an operating history as a drug company, or prior experience with obtaining regulatory, reimbursement or other approvals for product candidates such as DocePLUS;
- our Nanomedicine product candidates, if commercialized, will compete against established competitive drugs that are marketed and sold by large companies with significant human, technical and financial resources;
- we are not experienced in acquiring and integrating new assets;
- there is an intense and rapidly evolving competitive landscape for our Nanomedicine product candidates, including chemotherapies, targeted therapies and immuno-oncology therapies, and as such key assumptions regarding market entry, pricing, and revenue/unit share may not be realized;
- our product candidates may never become commercially viable; and
- we may not be able to prevent other companies from depriving us of market share and profit margins by selling products based on our intellectual property and developments.

We face intense competition, and if our competitors market and/or develop products that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities could be reduced or eliminated.

The life science industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including small and large, domestic and multinational, medical device, biotechnology and pharmaceutical companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we do.

We expect that product candidates in our pipeline, if approved, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage and reimbursement by third-party payers, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop other products that compete with ours, obtain necessary approvals for such products from the FDA, EMA, Ministry of Health, Labour and Welfare or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. The competition that we encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed may have an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. In addition, competitors may seek to develop alternative formulations of or technological approaches to our product candidates and/or drug delivery technologies that address our targeted indications.

We may face competition for our DocePLUS product candidate (which is intended for the treatment of small cell lung cancer) from multiple drug classes.

Companies that are developing or have commercialized nanoparticle-docetaxel products, including both oral and intravenous formulations, and may be future competitors for our DocePLUS product candidate include, but are not limited to, Adocia, Athenex, Bind Therapeutics, Cerulean, Cristal Therapeutics, Intas, LIDDS, Merrimack, Modra, NanOlogy, Oasmia, and Starpharma.

Competitors may have greater experience in developing drugs, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and experience;
- product development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name, brand and product recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more quickly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for our product candidates, which could prevent or significantly delay their regulatory approval and commercialization, which would have a material and adverse impact on our business.

Clinical testing of our product candidates is a long, expensive and uncertain process, and the failure or delay of a clinical trial can occur at any stage. Many factors, currently known and unknown, can adversely affect clinical trials and the ability to evaluate a product candidate's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if initial results of preclinical and nonclinical studies or clinical trial results are promising, we may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not obtain applicable regulatory approval for a variety of other reasons.

Further, with respect to the conduct and results of clinical trials generally, in the United States, Europe, Japan and other jurisdictions, the conduct and results of clinical trials can be delayed, limited suspended, or otherwise adversely affected for many reasons, including, among others:

- clinical results may not meet prescribed endpoints for the studies or otherwise provide sufficient data to support the efficacy of our product candidates;
- clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, and other third parties;
- inability to design appropriate clinical trial protocols;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- regulatory review may not find a product safe or effective enough to merit either continued testing or final approval;
- regulatory review may not find that the data from preclinical testing and clinical trials justifies approval;
- regulatory authorities may require that we change our studies or conduct additional studies which may significantly delay or make continued pursuit of approval commercially unattractive;
- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;
- the cost of clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product;

- a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities or the existing processes or facilities of our collaborators, our contract manufacturers or our raw material suppliers;
- a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations or raise new issues or concerns late in the approval process;
- a product candidate may be approved only for indications that are narrow or under conditions that place the product at a competitive disadvantage, which may limit the sales and marketing activities for such products or otherwise adversely impact the commercial potential of a product; and
- a regulatory agency may ask us to put a clinical study on hold pending additional safety data (and there can be no assurance that we will be able to satisfy the regulator agencies' requests in a timely manner, which can lead to significant uncertainty in the completion of a clinical study).

We also face clinical trial-related risks with regard to our reliance on other third parties in the performance of many of the clinical trial functions, including contract research organizations, that help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third-party service providers. Failure of any third-party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business.

Our success depends in substantial part on our ability to obtain regulatory approvals for our DocePLUS product candidate. However, we cannot be certain that we will receive regulatory approval for this product candidate or our other product candidates.

We have only a limited number of product candidates in development, and our business depends substantially on their successful development and commercialization. Our product candidates will require development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from sales of our product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries (including centralized marketing authorization from EMA), and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenues (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business.

Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed.

If a product candidate is not approved in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse effect on our business, and we may become more dependent on the development of other proprietary products and/or our ability to successfully acquire other products and technologies. There can be no assurance that any product candidate will receive regulatory approval in a timely manner, or at all.

If our product candidates and technologies receive regulatory approval but do not achieve broad market acceptance, especially by physicians, the revenues that we generate will be limited.

The commercial success of any of our approved products or technologies will depend upon the acceptance of these products and technologies by physicians, patients and the medical community. The degree of market acceptance of these products and technologies will depend on a number of factors, including, among others:

- acceptance by physicians and patients of the product as a safe and effective treatment;
- any negative publicity or political action related to our or our competitors' products or technologies;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- demonstration to authorities of the pharmacoeconomic benefits;
- demonstration to authorities of the improvement in burden of illness;
- limitations or warnings contained in a product's approved labeling;
- payers' level of restrictions and/or barriers to coverage;
- the clinical indications for which a product is approved;

- availability and perceived advantages of alternative treatments;
- the effectiveness of our or future collaborators' sales, marketing and distribution strategies; and
- pricing and cost effectiveness.

Our DocePLUS product candidate, if developed and commercialized, would compete against a number of established drugs, including Taxotere® (docetaxel) (Sanofi S.A.) and Hycamtin® (topotecan) (Novartis), as well as other products being developed and commercialized by competitors for the same target clinical indication.

We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future products. We believe we will continue to need to finance lengthy time-consuming clinical studies to provide evidence of the medical benefit of our products and resulting therapies in order to overcome this inertia and skepticism.

Overall, our efforts to educate the medical community on the benefits of any of our products or technologies for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products and technologies do not achieve an adequate level of acceptance by physicians, pharmacists and patients, we may not generate sufficient revenue from these products to become or remain profitable.

All potential applications of our product candidates are pre-commercial, which subjects us to development and marketing risks.

Our product candidates are at various stages of development. Successful development and market acceptance of our products is subject to developmental risks, including risk of negative clinical data from current and anticipated trials, failure of inventive imagination, ineffectiveness, lack of safety, unreliability, manufacturing hurdles, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, competition from copycat products and general economic conditions affecting purchasing patterns. There can be no assurance that we or our partners will successfully develop and commercialize our product candidates, or that our competitors will not develop competing technologies that are less expensive or superior. Failure to successfully develop and market our product candidates would have a substantial negative effect on our results of operations and financial condition.

If we or any party to a key collaboration, licensing, development, acquisition or similar arrangement fails to perform material obligations under such arrangement, or any arrangement is terminated for any reason, there could be an adverse effect on our business.

We are currently party to certain licensing, collaboration and acquisition agreements under which we may make or receive future payments in the form of milestone payments, maintenance fees, royalties and/or minimum product purchases. Our collaborators may not devote the attention and resources to such efforts to be successful. The termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators on favorable terms.

In February 2017, we acquired substantially all of the assets of Azaya Therapeutics Inc ("Azaya"), including DoxoPLUS and DocePLUS, and related manufacturing equipment and inventory pursuant to an asset purchase agreement (the "Azaya Purchase Agreement"). Under the Azaya Purchase Agreement, we are required to use commercial reasonable efforts to develop our DoxoPLUS and DocePLUS product candidates. Further, we are subject to future milestone, earn-out and other payments to Azaya all of which are tied to our commercialization and sale activities for these product candidates. If we are unsuccessful in our efforts to develop our DoxoPLUS and DocePLUS drug assets, or if Azaya and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed.

On March 29, 2020, the Company entered into an exclusive license agreement with NanoTx, Corp. ("NanoTx") for the global rights to develop and commercialize NanoTx's glioblastoma treatment. Under the license agreement with NanoTx, we are required to use commercial reasonable efforts to develop the assets acquired under the license agreement. Further, we are subject to future milestone, earn-out and other payments to NanoTx all of which are tied to our commercialization and sale activities for product candidates. If we are unsuccessful in our efforts to develop these assets, or if NanoTx and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed.

If we or collaborators fail to comply with regulatory requirements applicable to the development, manufacturing, and marketing of our products, regulatory agencies may take action against us or them, which could significantly harm our business.

Our product candidates, along with the clinical development process, the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and state and foreign regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We, our collaborators, and our and their respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising,

promotion and sales of products, required submissions of safety and other post-market information and reports, registration requirements, Clinical Good Manufacturing Practices (cGMP) regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies. We, our collaborators, and our and their respective contractors, suppliers and vendors, may be slow to adapt or may not be able to adapt to these changes or new requirements.

Failure to comply with regulatory requirements may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

We and our product candidates are subject to extensive regulation, and the requirements to obtain regulatory approvals in the United States and other jurisdictions can be costly, time-consuming and unpredictable. If we or our partners are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.

The worldwide regulatory process for our Nanomedicine drug candidates can be lengthy and expensive, with no guarantee of approval.

Before any new drugs may be introduced to the U.S. market, the manufacturer generally must obtain FDA approval through either an ANDA process for generic drugs off patent that allow for bioequivalence to an existing RLD or the lengthier NDA process, which typically requires multiple successful and successive clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. DocePLUS is subject to the FDA's 505(b)(2) NDA process. NDA drugs can take significant time due to the preclinical and clinical trial requirements.

There are numerous risks arising out of the regulation of our Nanomedicine product candidates include the following:

- we can provide no assurances that our current and future oncology drugs will meet all of the stringent government regulation in the United States, by the FDA under the Federal Food, Drug and Cosmetic Act, and/or in international markets such as Europe, by the EMA under its Medicinal Products Directive;
- our Nanomedicine product candidates, if approved, will still be subject to post-market reporting requirements for deaths or serious injuries when the drug may have caused or contributed to the death or serious injury, or serious adverse events;
- there are no assurances that our product candidates will not have safety or effectiveness problems occurring after the drugs reach the market;
- there are no assurances that regulatory authorities will not take steps to prevent or limit further marketing of the drug due to safety concerns; and
- it is possible that the new legislation in our priority markets will yield additional regulatory requirements for therapeutic drugs for our Nanomedicine product candidates.

Changing, new and/or emerging government regulations may adversely affect us.

Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we may be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business. Divergence in regulatory criteria for different regulatory agencies around the globe could result in the repeat of clinical studies and/or preclinical studies to satisfy local territory requirements, resulting in the repeating of studies and/or delays in the regulatory process. Some territories may require clinical data in their indigenous population, resulting in the repeat of clinical studies in whole or in part. Some territories may object to the formulation ingredients in the final finished product and may require reformulation to modify or remove objectionable

components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, Bovine Spongiform Encephalopathy and/or Transmissible Spongiform Encephalopathy risks, banned packaging components, prohibited chemicals, banned substances, etc. There can be no assurances that the FDA or foreign regulatory authorities will accept our pre-clinical and/or clinical data.

Anticipated or unanticipated changes in the way or manner in which the FDA or other regulators regulate products or classes/groups of products can delay, further burden, or alleviate regulatory pathways that were once available to other products. There are no guarantees that such changes in the FDA's or other regulators' approach to the regulatory process will not deleteriously affect some or all of our products or product applications.

Our nanoparticle technology and pipeline oncology products, such as DocePLUS, are being developed under existing government criteria, which are subject to change in the future. Clinical and/or pre-clinical criteria in addition to cGMP manufacturing requirements may change and impose additional regulatory burdens. Clinical requirements are subject to change which may result in delays in completing the regulatory process. Divergence in regulatory criteria for different regulatory agencies around the globe could result in the repeat of clinical studies and/or preclinical studies to satisfy local jurisdictional requirements, which would significantly lengthen the regulatory process and increase uncertainty of outcome. Some jurisdictions may require clinical data in their indigenous population, resulting in the repeat of clinical studies in whole or in part. Some jurisdictions may object to the formulation ingredients in the final finished product and may require reformulation to modify or remove objectionable components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, bovine spongiform encephalopathy/ transmissible spongiform encephalopathy risks, banned packaging components, prohibited chemicals, banned substances, etc. There can be no assurance that the FDA or foreign regulatory authorities will accept our pre-clinical and/or clinical data.

Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the U.S. Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 10,000 persons in the European Union. Currently, this designation provides market exclusivity in the U.S. and the European Union for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the European Union, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is "clinically superior" to the original orphan drug.

If we experience an interruption in supply from a material sole source supplier, our business may be harmed

We acquire some of our components and other raw materials from sole source suppliers. If there is an interruption in supply of our raw materials from a sole source supplier, there can be no assurance that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability or other issues with our sole source suppliers could have a negative impact on our ability to manufacture products and product candidates, which in turn could adversely affect the development and commercialization of our Nanomedicine product candidates and cause us to potentially breach our supply or other obligations under our agreements with certain other counterparties.

We are dependent on sole source suppliers to manufacture the active pharmaceutical ingredients (API) and certain other components of our Nanomedicine product candidates. There are no assurances that these sole source suppliers will enter into supply agreements with us to provide contractual assurance to us around supply and pricing. Regardless whether a sole source supplier enters into a written supply arrangement with us, such supplier could still delay, suspend or terminate supply of raw materials to us for a number of reasons, including manufacturing or quality issues, payment disputes with us, bankruptcy or insolvency, or other occurrences.

If a sole source supplier ceases supply of raw materials necessary there is no guarantee that we will find an alternative supplier for the necessary raw materials on terms acceptable to us, or at all. Further the qualification process for a new vendor could take months or even years, and any such day in qualification could significantly harm our business.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Growth of the Nanomedicine business will require significant management time and attention. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We must maintain quality assurance certification and manufacturing approvals.

The manufacture of our products is, and the manufacture of any future drug and/or cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of drugs and devices products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's cGMP, Quality System Regulations ("QSRs"), as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no assurance that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre- market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that after such occurrences that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

If we are unable to identify, hire and/or retain key personnel, we may not be able to sustain or grow our business.

We maintain a very small executive team. Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We compete for talent with numerous companies, as well as universities and non-profit research organizations. In the future, we may hire a significant number of scientists, quality and regulatory personnel, and other technical staff with the requisite expertise to support and expand our Nanomedicine business. The manufacturing of our oncology drug assets is a highly complex process that requires significant experience and know-how. If we are unable to attract personnel with the necessary skills and experience to reestablish and expand our Nanomedicine business, which is currently conducted out of our San Antonio, Texas facility, our business could be harmed.

Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. In particular, we are highly dependent on our executive officers, especially Marc Hedrick, M.D., our Chief Executive Officer. Given his leadership, extensive technical, scientific and financial expertise and management and operational experience, Dr. Hedrick would be difficult to replace. Consequently, the loss of services of Dr. Hedrick or any other executive officer could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenues. We do not maintain key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Our restructuring activities may not be successful, and our restructuring activities may cause uncertainty regarding the future of our business and may adversely impact employee hiring and retention, our stock price and our results of operations and financial condition.

On July 1, 2019, we announced a corporate restructuring, including reducing combined staffing in our Texas and California facilities by 46% overall, reducing our office space in San Diego, California and streamlining and outsourcing our operations to better focus on our drug pipeline, and in particular DocePLUS, in order to extend our cash resources. As a result, we expect to incur a restructuring charge of approximately $0.1 million in connection with one-time employee termination costs, including severance and other benefits, which costs primarily incurred in the third quarter of 2019. We are not yet able to make a determination of each other major type of cost associated with the restructuring. The estimates of costs that we expect to incur and the timing thereof are subject to a number of assumptions and actual results may differ from initial estimates.

Our ability to achieve the anticipated benefits, including the anticipated cost savings, of our restructuring activities within expected timeframes is subject to many estimates, assumptions and uncertainties. Additional restructuring or reorganization activities may also be required in the future, which could further increase the risks associated with these activities. There is no assurance that we will successfully implement, or fully realize the anticipated impact of, our restructuring or execute successfully on our restructuring plan, in the timeframes we desire or at all. If we fail to realize the anticipated benefits from these measures, or if we incur charges or costs in amounts that are greater than anticipated, our financial condition and operating results may be adversely affected. Additionally, our restructuring efforts, including a significant reduction in our employee headcount, may disrupt our staff and our business, and we may not be successful, or as successful, in advancing our existing Nanomedicine candidates, or in discovering or developing new Nanomedicine candidates as a result of lower staffing levels and potential reductions in our spending on these programs due to the restructuring.

The changes and potential changes to our operations and the workforce reduction measures as a result of the restructuring, may introduce uncertainty regarding our prospects and may result in disruption of our business. As a result of these actions, we incurred significant expenses and charges, including the approximately $570,000 charge incurred as a result of restructuring and cancelation of our San Diego headquarters lease announced on February 2018, and we may incur additional expenses and charges related to these actions. In addition, these changes and measures could distract our employees, decrease employee morale and make it more difficult to retain and hire new talent, and harm our reputation. These changes and activities caused our stock price to decline and may cause it to further decline in the future. As a result of these or other similar risks, our business, results of operations and financial condition may be adversely affected.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The clinical use of our product candidates exposes us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by applicable regulatory authorities and manufactured in facilities regulated by such authorities. Our product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. For example, DoxoPLUS is cytotoxic, or toxic to living cells, and, if incorrectly or defectively manufactured or labeled, or incorrectly dosed or otherwise used in a manner not contemplated by its label, could result in patient harm and even death. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for clinical trials with a $10 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act 2009 ("ARRA"), Congress amended the privacy and security provisions of the Healthcare Information Portability and Accountability Act ("HIPAA"). HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U.S. Department of Health and Human Services ("HHS"). Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union's Data Protection Directive, Canada's Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state/provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We and our collaborators must comply with environmental laws and regulations, including those pertaining to use of hazardous and biological materials in our business, and failure to comply with these laws and regulations could expose us to significant liabilities.

We and our collaborators are subject to various federal, state and local environmental laws, rules and regulations, including those relating to discharge of materials into the air, water and ground, those relating to manufacturing, storage, use, transportation and disposal of hazardous and biological materials, and those relating to the health and safety of employees with respect to laboratory activities required for the development of our products and activities. In particular, our Nanomedicine products and processes involve the controlled storage, use and disposal of certain cytotoxic, or toxic to living cells, materials. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials, or other violations of applicable environmental laws, rules or regulations cannot be completely eliminated. In the event of any violation of such laws, rules or regulations, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and could exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs in complying with environmental laws, rules and regulations.

Increased information technology security threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, and products.

Increased global information technology security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data and communications. While we attempt to mitigate these risks by employing a number of measures, including employee refreshers, monitoring of our networks and systems, and maintenance of backup and protective systems, our systems, networks and products remain potentially vulnerable to advanced persistent threats. Depending on their nature and scope, such threats could potentially lead to the compromising of confidential information and communications, improper use of our systems and networks, manipulation and destruction of data, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations.

The United Kingdom's departure from the European Union could adversely affect our business and financial results.

The United Kingdom held a referendum on June 23, 2016 in which a majority of voters voted to exit the European Union ("Brexit") and on March 29, 2017, the United Kingdom submitted a formal notification of its intention to withdraw from the European Union pursuant to Article 50 of the Treaty of Lisbon. As a result, the United Kingdom ceased to be a member state of the European Union on January 31, 2020. A transition period will apply until the end of 2020 (or later, if extended) during which the pre-Brexit legal regime will continue to apply (including with respect to aviation) while the United Kingdom and European Union negotiate rules that will apply to their future relationship. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, it is expected that the United Kingdom's regulatory regime will remain aligned to European Union regulations. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom. In the longer term, Brexit could materially impact us in the commercialization of our product candidates in the United Kingdom. In the short term, there is a risk of incremental costs and delays related to the marketing authorization and regulatory processes.

We may face business disruption and related risks resulting from the recent outbreak of the novel coronavirus 2019 (COVID-19), which could have a material adverse effect on our business.

Our development programs could be disrupted and materially adversely affected by the recent outbreak of COVID-19. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the International Health Regulations Emergency Committee of the World Health Organization declaring the outbreak of COVID-19 as a "public health emergency of international concern," and the World Health Organization characterizing COVID-19 as a pandemic. While the COVID-19 outbreak may still be in early stages, international stock markets have begun to reflect the uncertainty associated with the potential economic impact of the outbreak and the significant declines in the Dow Industrial Average at the end of February and in March 2020 has been largely attributed to the effects of COVID-19. We are still assessing the potential impact COVID-19 may have on our ability to effectively conduct our commercialization efforts and development programs and otherwise conduct our business operations as planned, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-019 or its consequences, including downturns in business sentiment generally or in our industry and business in particular.

Risks Relating to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our success depends in part on our ability to obtain and maintain patent, trademark and trade secret protection of our platform technology and current product candidates, including but not limited to our Nanomedicine product candidates, including DoxoPLUS and DocePLUS, as well as successfully defending our intellectual property against third-party challenges. Our ability to stop unauthorized third parties from making using selling, offering to sell or importing our platform technology and/or 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 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:

- we, or Azaya, as the case may be, might not have been the first to file patent applications for the covered inventions;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are dominating patents to our products of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our patents, of which we are not aware;
- it is possible that others may circumvent our patents;

- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the claims of our patents or patent applications, if and when issued, may not cover our system or products, or our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- others may be able to make or use compounds that are the same or similar to the DocePLUS product but that are not covered by the claims of our patents;
- we may not be able to detect infringement against our patents, which may be especially difficult for manufacturing processes or formulation patents, such as the patents/applications related to DocePLUS;
- the API in DoxoPLUS and DocePLUS are commercially available in generic drug products;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

The patent positions of pharmaceutical, biopharmaceutical and medical device 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 patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the USPTO and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Failure to obtain or maintain patent protection or protect trade secrets, for any reason (or third-party claims against our patents, trade secrets, or proprietary rights, or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition.

We may not be able to protect our trade secrets.

We may rely on trade secrets to protect our technology, especially with respect to the Nanomedicine products, as well as in areas where we do not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the Unites States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we 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. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

Litigation may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights, which would result in substantial costs to us and diversion of effort on our part. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the USPTO or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, reexamination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe the patents of third-parties, we may be subject to litigation, prevented from commercializing potential products in the relevant jurisdiction and/or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could adversely affect our business and results of operations.

Competitors or third parties may infringe on or upon our patents. We may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing.

Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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 or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued by others. There may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our products, proprietary technologies or their uses, we could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

Risks Relating to the Securities Markets and an Investment in Our Stock

The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- fluctuations in our operating results or the operating results of our competitors;
- the outcome of clinical trials involving the use of our products, including our sponsored trials;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- conditions and trends in the markets we currently serve or which we intend to target with our product candidates;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- our continuing ability to list our securities on an established market or exchange;
- the timing and outcome of regulatory reviews and approvals of our products;
- the commencement or outcome of litigation involving our company, our general industry or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by the holders of our common stock; and
- the trading volume of our common stock.

In addition, the stock market in general, the Nasdaq markets may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations, which may materially harm the market price of our common stock and result in substantial losses for stockholders.

Future sales of our common stock may depress our share price.

As of December 31, 2019, we had 3,880,588 shares of our common stock outstanding. Sales of a number of shares of common stock in the public market, could cause the market price of our common stock to decline. We may also sell additional common stock or securities convertible into or exercisable or exchangeable for common stock in subsequent public or private offerings or other transactions, which may adversely affect the market price of our common stock.

We have granted demand registration rights for the resale of certain shares of our common stock to each of Astellas Pharma Inc. and Green Hospital Supply, Inc. pursuant to common stock purchase agreements previously entered into with each of these stockholders. An aggregate of approximately 30,000 shares of our common stock are subject to these demand registration rights. If we receive a written request from any of these stockholders to file a registration statement under the Securities Act of 1933, as amended, or the Securities Act, covering its shares of unregistered common stock, we are required to use reasonable efforts to prepare and file with the SEC within 30 business days of such request a registration statement covering the resale of the shares for an offering to be made on a continuous basis pursuant to Rule 415 under the Securities Act.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of preferred stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders.

We could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital.

On August 16, 2019, we received a written notice from Nasdaq staff indicating that we no longer meet the minimum publicly held shares requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(4), which requires listed companies to maintain at least 500,000 publicly held shares. On September 11, 2019, we received written notice from Nasdaq staff that, based on having 786,807 publicly held shares outstanding as of August 31, 2019, we had regained compliance with Nasdaq Listing Rule 5550(a)(4).

However, on August 19, 2019, we received a written notice from Nasdaq staff indicating that, based on our stockholders' deficit of $6.3 million as of June 30, 2019, we no longer meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of December 31, 2019, we do not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations. We intend to evaluate various courses of action to regain compliance with Nasdaq Listing Rule 5550(b)(1) within the compliance period specified by Nasdaq. However, there can be no assurance that we will be able to regain compliance within such compliance period or, if we regain compliance, that we will not fall out of compliance with one of Nasdaq's continued listing standards at some future point in time.

If we cease to be eligible to trade on Nasdaq:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

We may be or become the target of securities litigation, which is costly and time-consuming to defend.

In the past, following periods of market volatility in the price of a company's securities, the reporting of unfavorable news or continued decline in a company's stock price, security holders have often instituted class action litigation. The market value of our securities has steadily declined over the past several years for a variety of reasons discussed elsewhere in this "Risk Factors" section, which heightens our litigation risk. If we face such litigation, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

Our charter documents contain anti-takeover provisions.

Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable. These provisions could also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- authorize our Board of Directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and cannot be taken by written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

We are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

We presently do not intend to pay cash dividends on our common stock.

We have never paid cash dividends in the past, and we currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. Furthermore, our Loan and Security Agreement with Oxford currently prohibits our issuance of cash dividends. This could make an investment in our common stock inappropriate for some investors, and may serve to narrow our potential sources of additional capital. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely, or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

There is currently a limited market for our securities, and any trading market that exists in our securities may be highly illiquid and may not reflect the underlying value of our net assets or business prospects.

Although our common stock is traded on the Nasdaq Capital Market, there is currently a limited market for our common stock and an active market may never develop. An active trading market in our common stock may not develop.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We have two lease agreements for our San Antonio, Texas locations. We pay an aggregate of approximately $12,000 in rent per month for these properties. The leases for these properties will expire in June 2022 or in 2028.

Item 3. Legal Proceedings

On July 25, 2019, Tap Advisors LLC (“Tap”) filed suit against the Company in the Supreme Court of the State of New York, County of New York, alleging the Company breached an agreement made in 2017, whereby Tap would provide certain financial advisory services to the Company. Tap sought to recover fees of approximately $3.7 million (plus attorneys’ fees) that allegedly had not been paid by the Company related to the sale of its cell therapy business in April 2019. In December 2019, the Company settled the Tap litigation with cash payment of $0.7 million.

From time to time, we have been involved in routine litigation incidental to the conduct of our business. As of December 31, 2019, other than discussed above, we were not a party to any material legal proceeding.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Prices

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "PSTV". As of March 20, 2020, we had approximately thirteen record holders of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these record holders.

Equity Compensation Plan Information

The following table gives information as of December 31, 2019 about shares of our common stock that may be issued upon the exercise of outstanding options, and shares remaining available for issuance under all of our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans not approved by security holders (1)	783	$ 5,728.06	30
Equity compensation plans approved by security holders (2)	1,082	$ 975.65	99,699
Total	1,865	$ 2,968.22	99,729

(1) Represents (i) options outstanding that were issued under the 2004 Stock Option and Stock Purchase Plan which expired in August 2004 and (ii) the 2015 New Employee Incentive Plan

(2) See Notes to the Consolidated Financial Statements included elsewhere herein for a description of our 2014 Equity Incentive Plan.

Material Features of the Amended and Restated 2015 New Employment Incentive Plan

The 2015 Plan was adopted by the Company on December 29, 2015 pursuant to Rule 5653(c)(4) of the Nasdaq Global Market. The 2015 Plan was subsequently amended by the Board in May 2016 and January 2020.

Awards granted under the 2015 Plan were intended to constitute "employment inducement awards" under Nasdaq Listing Rule 5635(c)(4) and, therefore, the 2015 Plan was intended to be exempt from the Nasdaq Listing Rules regarding stockholder approval of stock option and stock purchase plans. The 2015 Plan provides for issuance of 133 shares. In January 2017, the Company amended the 2015 Plan to add 500 shares to its share pool. In February 2020, the Company amended the 2015 Plan to add 250,000 shares of stock to its share pool. The 2015 Plan provided for the grant of restricted stock unit awards, restricted stock awards, performance awards, unrestricted securities, stock-equivalent units, stock appreciation units, securities or debentures convertible into common stock or other forms. These awards may have been granted to individuals who were then new employees, or were commencing employment with us or one of our subsidiaries following a bona fide period of non-employment with us, and for whom such awards were granted as a material inducement to commencing employment with us or one of our subsidiaries.

The 2015 Plan is administered by the Compensation Committee. The plan administrator has discretion to take action under the 2015 Plan, such as determining the purchase price, performance measures, any repurchase rights, as well as make adjustment to the terms of any Award to reflect, or related to, such changes in the capital structure of the Company or distributions as it deems appropriate, including modification of performance goals, performance award formulas, and performance periods.

Item 6. Selected Financial Data

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the discovery, development, and delivery of complex and innovative treatments for patients battling cancer and rare diseases.

Our proprietary nanotechnology platform is currently centered around the enhanced delivery of a variety of drugs using novel liposomal nanoparticle encapsulation technology. Liposomal nanoparticle encapsulation has been extensively explored and undergone significant technical and commercial advances since it was first developed. Our platform is designed to facilitate new delivery approaches and/or formulations of clinically proven therapies, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers.

We plan to leverage our nanotechnology platform and expertise using a simple multi-step model that enables us to address unmet needs or underserved conditions while managing risks and minimizing development costs through: (1) mapping of the current and anticipated market landscape to clearly understand the clinical and commercial opportunities and defining nanotechnology options, (2) redesign of known, safe and effective active pharmaceutical ingredients with new nanotechnology, (3) manufacture-to-scale of the reformulated drug along with critical non-clinical (i.e. bench, animal) analyses, (4) evaluation of early-stage clinical utility with a focus on proving safety and defining efficacy over the current standard of care, and (5) partnering the innovative treatment for late-stage clinical trials, regulatory approval, and commercial launch.

Recent developments

On March 29, 2020 the Company entered into a ninth amendment (the "Ninth Amendment") to the Loan and Security Agreement, pursuant to which, among other things, Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021. In addition, the Company made a $5.0 million paydown of principal upon execution of the Ninth Amendment. As a result of this Ninth Amendment, the term of the Term Loan has been extended from June 1, 2021 to June 1, 2024, with all other major terms remaining consistent.

On March 29, 2020 the Company entered into an exclusive license agreement with NanoTx for global development and commercialization of its glioblastoma treatment. Once certain post transaction requirements are met, the Company will make an initial license fee payment of $400,000 in cash and $300,000 in the Company's common stock, based on a mutually agreed upon price consisting of the Company's weighted average closing stock prices prior to issuance of such shares of common stock. This license agreement commits the Company to certain milestone payments to NanoTx upon successful completion of various milestones, together with royalty and sales payments based on the successful commercialization of the treatment.

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company's financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation on its financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for fiscal year 2020.

Results of Operations

Development revenue

Under our government contract with BARDA, we recognized a total of $7.0 million and $3.0 million in development revenues for the years ended December 31, 2019 and 2018, respectively which included allowable fees as well as cost reimbursements. During the years ended December 31, 2019 and 2018, we incurred $1.5 million and $2.7 million in qualified expenditures, respectively.

The increase in revenues for the year ended December 31, 2019 as compared to 2018 is primarily due to $4.6 million of revenue recognized during 2019 under the BARDA contract based on retrospective changes in indirect cost rates during fiscal years 2012 through 2019.

On July 21, 2019, we received an order from BARDA to suspend all work related to the RELIEF clinical trial, except for certain activities related to orderly close out of the trial and contract. Pursuant to the order, the contract with BARDA was terminated by December 31, 2019.

Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our product candidates, payment of regulatory fees, laboratory supplies, pre-clinical studies and clinical studies.

The following table summarizes the components of our research and development expenses for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,	
	2019	2018
Research and development	$ 5,325	$ 5,464
Share-based compensation	40	59
Total research and development expenses	$ 5,365	$ 5,523

Research and development related profession services expenses decreased by approximately $0.5 million for the year ended December 31, 2019, compared with the same period in 2018, offset by an increase of approximately $0.4 million in product studies.

We expect aggregate research and development expenditures in 2020 to remain in line in absolute dollars in 2019. Our current research and development expenditures are focused on process characterization, analytical method development and validation for the manufacturing of ATI 1123 (Liposomal Docetaxel). In 2020, we also intend to focus on the technology transfer of the drug product manufacture to a contract drug manufacturing organization in preparation for clinical builds in support of a phase II trial.

Sales and marketing expenses

Sales and marketing expenses include costs of sales and marketing personnel, events and tradeshows, customer and sales representative education and training, primary and secondary market research, and product and service promotion. The following table summarizes the components of our sales and marketing expenses for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,	
	2019	2018
Sales and marketing	$ 457	$ 617
Share-based compensation	11	26
Total sales and marketing expenses	$ 468	$ 643

Sales and marketing expenses decreased by $0.2 million for the year ended December 31, 2019 as compared to the same period in 2018 primarily due to decreases of $0.2 million in salaries and benefits related to decreased headcount.

We expect sales and marketing expenditures to remain at similar levels in 2020 as they were in 2019.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,	
	2019	2018
General and administrative	$ 4,746	$ 5,350
Share-based compensation	76	229
Total general and administrative expenses	$ 4,822	$ 5,579

General and administrative expenses decreased by $0.8 million for the year ended December 31, 2019, as compared to 2018 primarily due to decreases of $0.6 million in rent expenses and related overhead costs, and $0.2 million in professional services expenses.

We expect general and administrative expenditures to decrease in absolute dollars in 2020 as compared with 2019.

Share-based compensation expenses

Share-based compensation expenses include charges related to options and restricted stock awards issued to employees, directors and non-employees. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

The following table summarizes the components of our share-based compensation expenses for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,	
	2019	2018
Research and development-related	40	$ 59
Sales and marketing-related	11	26
General and administrative-related	76	229
Total share-based compensation	$ 127	$ 314

The decrease in share-based compensation expenses for the year ended December 31, 2019 as compared to 2018 is primarily related to a delayed annual grant to directors and officers, as well as lower annual grant activity to remaining employees caused by reductions in headcount and its corresponding impact on share-based compensation.

We expect to continue to grant options and stock awards (which will result in an expense) to our employees, directors, and, as appropriate, to non-employee service providers. In addition, previously-granted options will continue to vest in accordance with their original terms. As of December 31, 2019, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately $58,000 which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.39 years.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the years ended December 31, 2019 and 2018 (in thousands):

	Years ended December 31,	
	2019	2018
Interest income	55	43
Interest expense	(1,855)	(1,922)
Change in fair value of warrants	3,407	2,233
Issuance cost of warrants	(1,233)	(470)
Total	$ 374	$ (116)

Interest expense decreased for the year ended December 31, 2019 as compared to 2018, due to principal payments made on our debt in 2019.

The gain in fair value of our warrant liability for the year ended December 31, 2019 is primarily due to the decrease in stock price related to the warrants issued in connection with the financing raised in September 2019. The gain in fair value of our warrant liability for the year ended December 31, 2018, is primarily due to the decrease in stock price related to the warrants issued in connection with the issuance of Series C Convertible Preferred Stock in July 2018.

Issuance cost of warrants for the year ended December 31, 2019 was related to the warrants issued in connection with financing raised in September 2019. Issuance cost of warrants for the year ended December 31, 2018 was related to warrants issued in connection with the Rights Offering in July 2018.

We expect interest expense in 2020 to decrease with the amortization of the principal balance of our term loan.

Discontinued Cell Therapy Business

All revenues, and related operating and nonoperating expenses have been classified as discontinued operations in accordance with authoritative accounting guidance.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures (for continuing operations) at December 31, 2019 and 2018 (in thousands):

	As of December 31,	
	2019	2018
Cash and cash equivalents	$ 17,552	$ 5,261
Current assets	$ 19,825	$ 6,371
Current liabilities	14,486	16,979
Working capital (deficit)	$ 5,339	$ (10,608)

We incurred net losses of $10.9 million for the year ended December 31, 2019. We have an accumulated deficit of $425.3 million as of December 31, 2019. Additionally, we used net cash of $5.9 million to fund our operating activities for the year ended December 31, 2019. These factors raise substantial doubt about the Company's ability to continue as a going concern.

To date, our operating losses have been funded primarily from outside sources of invested capital including our recently completed September 2019 Offering (defined below), 2018 Rights Offering (defined below), our Lincoln Park Purchase Agreement (defined below) with Lincoln Park Capital Fund, LLC ("Lincoln Park"), the 2017 Rights Offering (defined below), the Loan and Security Agreement and gross profits. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash would have a material adverse impact on operations and would likely cause us to default on our loan.

On March 29, 2020 the Company entered into the Ninth Amendment, pursuant to which, among other things, Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021. In addition, the Company made a $5.0 million paydown of principal upon execution of the Ninth Amendment. As a result of this Ninth Amendment, the term of the Term Loan has been extended from June 1, 2021 to June 1, 2024, with all other major terms remaining consistent.

In September 2019, we finalized the indirect cost rate under the BARDA Agreement for indirect costs incurred during the years 2012 through 2019, which resulted in approximately $4.6 million of revenue recognized during the year ended December 31, 2019.

In September 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the "Representative"), as representative of the underwriters (the "Underwriters"), pursuant to which we sold in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value $0.001 per share, of the Company and one Series U Warrant to purchase one share of common stock, and (ii) 2,711,000 Class B Units, each consisting of one pre-funded Series V Warrant to purchase one share of common stock and one Series U Warrant to purchase one share of common stock at a public offering price of $5.00 per Class A Unit and $4.9999 per Class B Unit ("September 2019 Offering"). In addition, we granted the Underwriters a 45-day option to purchase up to an additional 450,000 shares of our common stock and/or Series U warrants at the public offering price, less the underwriting discounts and commissions. The Underwriters exercised their option to purchase an additional 450,000 Series U warrants. We also issued to the Representative warrants (in the form of the Series U warrants) to purchase 75,000 shares of common stock with an exercise price of $6.25 per share of common stock ("Representative Warrants").

On April 24, 2019 we received $3.3 million of net cash proceeds related to the sale of the UK Subsidiary and our Cell Therapy assets (excluding such assets used in Japan or relating to the our contract with BARDA), of which $1.7 million was used to pay down principal, interest and fees on the Loan and Security Agreement, and on April 25, 2019 we received $2.4 million of net cash proceeds related to the sale of the Japanese Subsidiary, and substantially all of our Cell Therapy assets used in Japan, of which $1.4 million was used to pay down principal, interests and fees on the Loan and Security Agreement.

In August 2019, we consummated a 1-for-50 reverse stock split pursuant to which the minimum bid price of our common stock rose above $1.00 in order to regain compliance with the Nasdaq Stock Market Listing Rule 5550(a)(2) concerning the minimum bid price per share of our common stock.

Based on our stockholders' equity of $1.2 million as of December 31, 2019, we do not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). We expect to receive written notice from Nasdaq staff to that effect following the filing of this Annual Report on Form 10-K.

We continue to seek additional capital through strategic transactions and other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

The accompanying consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and 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 uncertainty related to our ability to continue as a going concern.

Cash (used in) provided by operating, investing and financing activities for the years ended December 31, 2019 and 2018 is summarized as follows (in thousands):

	Years Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (5,906)	$ (11,975)
Net cash used in investing activities	5,570	(133)
Net cash provided by financing activities	12,631	7,168
Effect of exchange rate changes on cash and cash equivalents	(4)	16
Net increase (decrease) in cash and cash equivalents	$ 12,291	$ (4,924)

Operating activities

Net cash used in operating activities for the year ended December 31, 2019 was $5.9 million. Overall, our operational cash use decreased during the year ended December 31, 2019 as compared to 2018 due primarily to a decrease in losses from operations (when adjusted for non-cash items) of $6.0 million.

Investing activities

The net cash provided by investing activities for the year ended December 31, 2019, as compared to 2018, resulted primarily from cash received from sale of our Cell Therapy business of $5.6 million received in 2019.

Financing Activities

The net cash provided by financing activities for the year ended December 31, 2019 is primarily related to sales of common stock and warrants of $16.0 million, net of costs from sale, from our September 2019 Offering, and $0.5 million from exercise of warrants, offset by repayment of debt principle of $3.7 million.

The net cash provided by financing activities for the year ended December 31, 2018 is primarily related to sales of common and preferred stock of $7.2 million, net of offering-related expenses, through our 2018 Rights Offering.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Significant Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively as we become aware of the necessity for an adjustment.

We believe it is important for you to understand our most critical accounting policies. These are our policies that require us to make our most significant judgments and, as a result, could have the greatest impact on our future financial results.

Impairment

We assess certain of our long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. There was no impairment in 2019 or 2018.

G***oodwill***

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. The goodwill is considered to be impaired if we determine that the carrying value of the reporting unit exceeds its respective fair value. We perform the annual impairment analysis by comparing our estimated fair value, calculated from our market capitalization, to our carrying amount. In connection with the sale of our Cell Therapy business, we disposed approximately $3.5 million of goodwill that was attributed to the businesses sold. As of December 31, 2019, we had $0.4 million of remaining goodwill related to our ongoing business. Our annual evaluation for impairment of goodwill consists of one reporting unit. We completed our most recent annual evaluation for impairment as of November 30, 2019, and determined that no impairment existed and, consequently, no impairment charge has been recorded during the year.

Warrant Liability

Warrants issued in connection with the September 2019 Offering and 2018 Rights Offering do not trade in an active securities market, and as such, we estimate the fair value of these warrants using an option pricing model. Following the authoritative accounting guidance, warrants with variable exercise price features or with potential cash settlement outside control of the Company are accounted for as liabilities, with changes in the fair value included in operating expenses. We estimated the fair value of the warrants using the option pricing model.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements included elsewhere herein for disclosure and discussion of new accounting standards.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Plus Therapeutics, Inc.
Austin, Texas

Opinion on the Consolidated Financial Statements
We have audited the accompanying consolidated balance sheets of Plus Therapeutics, Inc. (the "Company") (formerly Cytori Therapeutics, Inc.) as of December 31, 2019 and 2018 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Method Related to Leases

As discussed in Notes 2 and 7 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Codification Topic 842, *Leases*.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

San Diego, California
March 30, 2020

PLUS THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	As of December31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 17,552	$ 5,261
Accounts receivable	1,169	178
Restricted cash	40	40
Inventories, net	107	107
Other current assets	957	785
Current assets held for sale	—	3,277
Total current assets	19,825	9,648
Property and equipment, net	2,179	2,299
Operating lease right-use-of assets	781	—
Other assets	72	39
Noncurrent assets held for sale	—	11,633
Goodwill	372	372
Total assets	$ 23,229	$ 23,991
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,279	$ 2,777
Operating lease liability	147	—
Term loan obligation, net of discount	11,060	14,202
Current liabilities held for sale	—	580
Total current liabilities	14,486	17,559
Other noncurrent liabilities	8	46
Noncurrent operating lease liability	646	—
Warrant liability	6,929	916
Noncurrent liabilities held for sale	—	245
Total liabilities	22,069	18,766
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,959 and 4,606 shares issued and outstanding in 2019 and 2018, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 3,880,588 and 296,609 shares issued and outstanding in 2019 and 2018, respectively	4	—
Additional paid-in capital	426,426	418,390
Accumulated other comprehensive income	—	1,218
Accumulated deficit	(425,270)	(414,383)
Total stockholders' equity	1,160	5,225
Total liabilities and stockholders' equity	$ 23,229	$ 23,991

See Accompanying Notes to these Consolidated Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	For the Years Ended December 31,	
	2019	2018
Development revenues:		
Government contracts and other	$ 6,998	$ 2,983
	6,998	2,983
Operating expenses:		
Research and development	5,365	5,523
Sales and marketing	468	643
General and administrative	4,822	5,579
Total operating expenses	10,655	11,745
Operating loss	(3,657)	(8,762)
Other income (expense):		
Interest income	55	43
Interest expense	(1,855)	(1,922)
Change in fair value of warrants	3,407	2,233
Issuance cost of warrants	(1,233)	(470)
Total other expense	374	(116)
Loss from continuing operations	$ (3,283)	$ (8,878)
Loss from discontinued operations	(7,604)	(3,756)
Net loss	$ (10,887)	$ (12,634)
Income (Loss) from continuing operations	$ (3,283)	$ (8,878)
Beneficial conversion feature for convertible preferred stock	(554)	(2,487)
Net loss allocable to common stockholders - continuing operations	$ (3,837)	$ (11,365)
Net loss allocable to common stockholders - discontinued operations	(7,604)	(3,756)
Net loss allocable to common stockholders	$ (11,441)	$ (15,121)
Basic and diluted net loss per share attributable to common stockholders - continuing operations	$ (2.77)	$ (65.37)
Basic and diluted net loss per share attributable to common stockholders - discontinued operations	(5.49)	(21.61)
Net loss per share, basic and diluted	$ (8.27)	$ (86.98)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	1,384,012	173,851
Comprehensive loss:		
Net loss	$ (10,887)	$ (12,634)
Other comprehensive loss – foreign currency translation adjustments	—	(169)
Comprehensive loss	$ (10,887)	$ (12,803)

See Accompanying Notes to these Consolidated Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018
(in thousands, except share data)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	2,431	$ —	115,651	$ —	$ 413,362	$ 1,387	$ (401,749)	$ 13,000
Share-based compensation	—	—	—	—	355	—	—	355
Sale of common stock, net	—	—	92,169	—	1,624	—	—	1,624
Issuance of Series C Convertible Preferred Stock into common stock, net	6,723	—	—	—	3,041	—	—	3,041
Conversion of Series C Convertible Preferred Stock into common stock	(3,228)	—	80,868	—	8	—	—	8
Conversion of Series B Convertible Preferred Stock into common stock	(1,320)		7,921	—	—	—	—	—
Beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	2,487	—	—	2,487
Accretion of beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	(2,487)	—	—	(2,487)
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(169)	—	(169)
Net loss	—	—	—	—	—	—	(12,634)	(12,634)
Balance at December 31, 2018	4,606	$ —	296,609	$ —	$ 418,390	$ 1,218	$ (414,383)	$ 5,225
Share-based compensation	—	—	—	—	127	—	—	127
Sale of common stock, pre-funded warrants and warrants for common stock, net of offering costs of $0.6 million	—	—	3,000,000	4	4,417	—	—	4,421
Sale of common stock, net	—	—	184,666	—	2,208	—	—	2,208
Conversion of Series B and Series C Convertible Preferred Stock into common stock	(2,647)	—	334,199	—	—	—	—	—
Exercise of warrants	—	—	65,114	—	490	—	—	490
Warrant derivative liability reclasssified to equity due to exercise of warrants	—	—	—	—	794	—	—	794
Beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	554	—	—	554
Accretion of beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	(554)	—	—	(554)
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(1,218)	—	(1,218)
Net loss	—	—	—	—	—	—	(10,887)	(10,887)
Balance at December 31, 2019	1,959	$ —	3,880,588	$ 4	$ 426,426	$ —	$ (425,270)	$ 1,160

See Accompanying Notes to these Consolidated Financial Statements

PLUS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,	
	2019	**2018**
Cash flows used in operating activities:		
Net loss	$ (10,887)	$ (12,634)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	896	2,004
Amortization of deferred financing costs and debt discount	550	578
Change in fair value of warrants	(3,407)	(2,233)
Allocation of issuance cost associated with warrants	1,233	470
Share-based compensation expense	127	355
Noncash lease expense	12	
Loss on sale of business	6,508	—
Loss on asset disposal	—	36
Provision for doubtful accounts	—	18
Provision for excess inventory	—	463
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(1,203)	(173)
Inventories	259	475
Other current assets	(211)	85
Other assets	263	23
Accounts payable and accrued expenses	(28)	(1,532)
Deferred revenues	29	73
Other long-term liabilities	(47)	17
Net cash used in operating activities	(5,906)	(11,975)
Cash flows from (used in) investing activities:		
Purchases of property and equipment	(67)	(133)
Proceeds from sale of business	5,637	—
Net cash provided by (used in) investing activities	5,570	(133)
Cash flows from financing activities:		
Principal payments of long-term obligations	(3,692)	—
Payment of financing lease liability	(131)	-
Proceeds from sale of common stock and unit offering, net of offering cost	15,964	—
Proceeds from exercise of warrants	490	—
Proceeds from sale of common and preferred stock	—	7,234
Financial capital expenditures	—	(66)
Net cash provided by financing activities	12,631	7,168
Effect of exchange rate changes on cash and cash equivalents	(4)	16
Net increase (decrease) in cash and cash equivalents	12,291	(4,924)
Cash, cash equivalents, and restricted cash at beginning of period	5,301	10,225
Cash, cash equivalents, and restricted cash at end of period	$ 17,592	$ 5,301
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 1,188	$ 1,331
Supplemental schedule of non-cash investing and financing activities:		
Proceeds from sales of business, net, paid directly to lender for principal payment of long-term obligations	$ 3,050	$ —
Offering cost paid in warrants	$ 213	$ —
Reclass of warrants upon exercise from liability to equity	$ 794	$ —
Fair value of Convertible Preferred Stock beneficial conversion feature	$ 554	$ 2,487
Conversion of preferred stock into common	$ —	$ 8

See Accompanying Notes to these Consolidated Financial Statements

1. Organization and Operations

The Company

Plus Therapeutics, Inc. (formerly known as Cytori Therapeutics, Inc.) is a clinical-stage pharmaceutical company focused on the discovery, development, and manufacturing scale up of complex and innovative treatments for patients battling cancer and other life-threatening diseases.

Principles of Consolidation

The accompanying consolidated financial statements include the Company's accounts and those of its subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

Up to the sale transactions as described below, the Company had five wholly-owned subsidiaries located in Japan, United Kingdom, Switzerland, India and Spain that have been established primarily to support our sales and marketing activities in these regions.

On March 30, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the "Lorem Purchase Agreement") with Lorem Vascular Pte. Ltd. ("Lorem"), pursuant to which, among other things, Lorem agreed to purchase the Company's UK subsidiary, Cytori Ltd. (the "UK Subsidiary"), and the Company's Cell Therapy assets, excluding such assets used in Japan or relating to the Company's contract with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA"). Both the Company and Lorem made customary representations, warranties and covenants in the Lorem Purchase Agreement. The transaction was completed on April 24, 2019 and the Company received $4.0 million of cash proceeds, of which $1.7 million was used to pay down principal, interest and fees under the Loan and Security Agreement, dated May 29, 2015 (the "Loan and Security Agreement"), with Oxford Finance, LLC ("Oxford").

On April 19, 2019, the Company entered into an Asset and Share Sale and Purchase Agreement (the "Shirahama Purchase Agreement") with Seijirō Shirahama, pursuant to which, among other things, Mr. Shirahama agreed to purchase the Company's Japanese subsidiary, Cytori Therapeutics, K.K. (the "Japanese Subsidiary"), and substantially all of the Company's Cell Therapy assets used in Japan. Both the Company and Mr. Shirahama made customary representations, warranties and covenants in the Shirahama Purchase Agreement. The transaction was completed on April 25, 2019 and the Company received $3.0 million of cash proceeds, of which $1.4 million was used to pay down principal, interest and fees under the Loan and Security Agreement (defined in Note 4).

Amendments to Certificate of Incorporation and Reverse Stock Split

On July 29, 2019, the Company amended its Certificate of Incorporation with the State of Delaware to change its corporate name from Cytori Therapeutics, Inc. to Plus Therapeutics, Inc. The Company also changed its trading symbol for its common stock on the Nasdaq Capital Market to "PSTV".

On May 23, 2018, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to (i) effectuate a one-for-ten (1:10) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value, and (ii) increase the number of authorized shares of the Company's common stock from 75 million to 100 million shares (which amount is not otherwise affected by the Reverse Stock Split). The Amendment became effective on the filing date. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company's common stock (x) issued and outstanding decreased from approximately 61.6 million shares (as of May 23, 2018) to approximately 6.2 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 23.4 million shares to approximately 2.3 million shares, and (z) reserved but unallocated under our current equity incentive plans (including the stockholder-approved share increase to the Company's 2014 Equity Incentive Plan) decreased from approximately 9.1 million common shares to approximately 0.9 million common shares. The Company's 5,000,000 shares of authorized Preferred Stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Proportional adjustments for the reverse stock split were made to the Company's outstanding stock options, warrants and equity incentive plans for all periods presented.

On August 5, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment (the "August 2019 Amendment") to its Amended and Restated Certificate of Incorporation (the Amendment), as amended, with the Secretary of State of the State of Delaware to effectuate a one-for-fifty (1:50) reverse stock split (the "August 2019 Reverse Stock Split")) of its common stock, par value $0.001 per share, without any change to its par value. The August 2019 Amendment became effective on the filing date. The August 2019 Reverse Stock Split became effective for trading purposes as of the commencement of trading on the Nasdaq Capital Market on August 6, 2019. Upon effectiveness, each 50 shares of issued and outstanding common stock were converted into one newly issued and outstanding share of common stock. The Company's 5,000,000 shares of authorized Preferred Stock were not affected by the August 2019 Reverse Stock Split. No fractional shares were issued in connection with the August 2019 Reverse Stock Split. Any fractional shares of common Stock that would have otherwise resulted from the August 2019 Reverse Stock Split were rounded up to the nearest whole share. Outstanding equity awards and the shares available for future grant under the Company's 2014 Amended and Restated Equity Incentive Plan and 2015 New Employee Incentive Plan were proportionately reduced (rounded down to the nearest whole share), and the exercise prices of outstanding equity awards were proportionately increased (rounded up to the nearest whole cent) to give effect to the August 2019 Reverse Stock Split.

Certain Risks and Uncertainties

The Company's prospects are subject to the risks and uncertainties frequently encountered by companies in the early stages of development and commercialization, especially those companies in rapidly evolving and technologically advanced industries such as the biotech/medical device field. The Company's future viability largely depends on its ability to complete development of new products and receive regulatory approvals for those products. No assurance can be given that the Company's new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved.

Liquidity and Going Concern

The Company incurred net losses of $10.9 million for the year ended December 31, 2019, and it had an accumulated deficit of $425.3 million as of December 31, 2019. Additionally, the Company used net cash of $5.9 million to fund its operating activities for the year ended December 31, 2019. In addition, as discussed in Note 13, the full magnitude of the coronavirus pandemic on the Company's financial condition, liquidity and future results of operations is uncertain. These factors raise substantial doubt about the Company's ability to continue as a going concern.

In September 2019, the Company finalized the indirect cost rate under the BARDA Agreement for indirect costs incurred during the years 2012 through 2019, which resulted in approximately $4.6 million of revenue recognized during the year ended December 31, 2019.

In September 2019, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (the "Representative"), as representative of the underwriters (the "Underwriters"), pursuant to which the Company sold in an underwritten public offering an aggregate of (i) 289,000 Class A Units, each consisting of one share of common stock, par value $0.001 per share, of the Company and one Series U warrant to purchase one share of common stock, and (ii) 2,711,000 Class B Units, each consisting of one pre-funded Series V warrant to purchase one share of common stock and one Series U Warrant to purchase one share of common stock at a public offering price of $5.00 per Class A Unit and $4.9999 per Class B Unit ("September 2019 Offering"). In addition, the Company granted the Underwriters a 45-day option to purchase up to an additional 450,000 shares of the Company's common stock and/or Series U Warrants at the public offering price, less the underwriting discounts and commissions. The Underwriters exercised their option to purchase an additional 450,000 Series U warrants. The Company also issued to the Representative warrants (in the form of the Series U warrants) to purchase 75,000 shares of common stock with an exercise price of $6.25 per share of common stock ("Representative Warrants").

On April 24, 2019, the Company received $3.3 million of net cash proceeds related to the sale of the UK Subsidiary and the Cell Therapy assets (excluding such assets used in Japan or relating to the Company's contract with BARDA), of which $1.7 million was used to pay down principal, interest and fees on the Loan and Security Agreement, and on April 25, 2019 the Company received $2.4 million of net cash proceeds related to the sale of the Japanese Subsidiary, and substantially all of the Company's Cell Therapy assets used in Japan, of which $1.4 million was used to pay down principal, interests and fees on the Loan and Security Agreement.

On September 21, 2018, the Company entered into a purchase agreement and a registration rights agreement ("Lincoln Park Purchase Agreement"), with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to $5.0 million of shares of the Company's common stock over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately $0.3 million through the Lincoln Park Purchase Agreement. During the year ended December 31, 2019, the Company sold 32,170 shares of through the Lincoln Park Purchase Agreement for proceeds of

approximately $0.3 million. The Company believes there an insignificant amount remaining available under this financing facility.

On June 1, 2018, the Company entered into a Sales Agreement with B. Riley FBR, Inc. ("B. Riley FBR") to sell shares of its common stock having an aggregate offering price of up to $6.5 million from time to time, through an "at the market" equity offering program (the "ATM program") under which B. Riley FBR will act as sales agent. The ATM Program financing facility has been exhausted and there is no availability remaining under this financing facility.

On July 25, 2018, the Company closed a rights offering originally filed under a Form S-1 registration statement in April 2018 ("2018 Rights Offering"). Pursuant to the 2018 Rights Offering, the Company sold an aggregate of 6,723 units consisting of a total of 6,723 shares of Series C Convertible Preferred Stock, resulting in total net proceeds to the Company of approximately $5.7 million. Refer to Note 11 for additional details on the 2018 Rights Offering.

On August 28, 2018, the Company received a written notice from Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, the Company no longer meet the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. The Company was granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of the Company's common stock must have been at least $1.00 per share for a minimum of ten consecutive business days during the 180-day period.

In August 2019, the Company consummated a 1-for-50 reverse stock split pursuant to which the minimum bid price of our common stock rose above $1.00. On August 29, 2019, the Company received written notice from Nasdaq staff that the Company had regained compliance with the Nasdaq Stock Market Listing Rule 5550(a)(2) concerning our minimum bid price per share of its common stock.

On August 16, 2019, the Company received written notice from the Nasdaq indicating that the Company no longer meets the requirements for continued listing under Nasdaq Listing Rule 5550(a)(4) due to the Company's failure to meet the minimum 500,000 publicly held shares requirement for continued listing. On September 11, 2019, we received written notice from Nasdaq staff that, based on having 786,807 publicly held shares outstanding as of August 31, 2019, we had regained compliance with Nasdaq Listing Rule 5550(a)(4).

On August 19, 2019, the Company received written notice from Nasdaq indicating that, based on the Company's stockholders' deficit of $6.3 million as of June 30, 2019, as reported in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, it is no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain stockholders' equity of at least $2.5 million.

Based on the Company's stockholders' equity of $1.2 million as of December 31, 2019, the Company does not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). The Company expects to receive written notice from Nasdaq staff to that effect following the filing of this Annual Report on Form 10-K.

The Company continues to seek additional capital through strategic transactions and from other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding to make debt repayments, for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, the Company will at a minimum need to significantly reduce or curtail its research and development and other operations, and this would negatively affect its ability to achieve corporate growth goals.

Should the Company fail to raise additional cash from outside sources, this would have a material adverse impact on its operations.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and 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 uncertainty related to its ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. The most significant estimates and critical accounting policies involve recognizing revenue, reviewing assets for impairment, determining the assumptions used in measuring share-based compensation expense, valuing warrants and valuing allowances for doubtful accounts.

Actual results could differ from these estimates. Management's estimates and assumptions are reviewed regularly, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

Cash and cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents.

Cash and cash equivalents includes cash in readily available checking and savings accounts. The Company held no investments as of December 31, 2019 and 2018. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held.

Restricted Cash

Restricted cash consists of cash invested in certificate of deposits used as collateral for the issuance of letters of credit pursuant to lease agreements for leasing of property at 3020 and 3030 Callan Road, San Diego, CA, which requires us to execute a letter of credit for $40,000 and $40,000 naming the landlord as a beneficiary as of December 31, 2019 and 2018, respectively.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. As of December 31, 2019, accounts receivable represents outstanding invoices under the contract BARDA for work performed prior to the BARDA contract termination.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation expense, which includes the amortization of capitalized leasehold improvements, is provided for on a straight-line basis over the estimated useful lives of the assets, or the life of the lease, whichever is shorter, and range from three to five years. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is included in operations. Maintenance and repairs are charged to operations as incurred.

Impairment

The Company assesses its property and equipment for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. The Company recognized no impairment losses during any of the periods presented in these financial statements.

Goodwill

The Company's goodwill represents the excess of the cost over the fair value of net assets acquired from its business combinations. The determination of the value of goodwill arising from business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired.

Goodwill is not amortized; however, it is assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. Goodwill considered to be impaired if the Company determines that the carrying value of the reporting unit exceeds its fair value.

The Company performs its impairment test annually during the fourth quarter by comparing the Company's estimated fair value, calculated from the Company's market capitalization, to its carrying amount. The Company's annual evaluation for impairment of goodwill consists of one reporting unit. The Company completed its most recent annual evaluation for impairment as of December 31, 2019, and determined that no impairment existed and, consequently, no impairment charge has been recorded during the year.

Warrant Liability

Warrants are accounted for in accordance with the applicable authoritative accounting guidance as either derivative liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities in the consolidated statements of operations and comprehensive loss.

	As of December 31, 2019	As of December 31, 2018
Expected term	1.1 years	2.1 years
Common stock market price	$ 2.40	$ 14.50
Risk-free interest rate	1.59%	2.48%
Expected volatility	168%	125%
Resulting fair value (per warrant)	$ 1.47	$ 6.50

Expected volatility was computed using daily pricing observations of traded shares of the Company for recent periods that correspond to the expected term of the warrants. The Company believes this method produces an estimate that is representative of our expectations of future volatility over the expected term of these warrants. The Company currently has no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is based on the remaining contractual term of the warrants. The risk-free interest rate is the U.S. Treasury bond rate as of the valuation date.

Fluctuations in the fair value of the warrants are impacted by unobservable inputs. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value measurement.

Refer to Note 3 for a discussion of the change in the Level 3 warrant liability value.

Revenue Recognition

Development Revenues

The Company earns revenue for performing tasks under research and development agreements with governmental agencies like BARDA. Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with government contracts are recorded as government contract and other within development revenues. Government contract revenue is recorded at the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in our statements of operations. The Company recognized $7.0 million and $3.0 million in BARDA revenue for the years ended December 31, 2019 and 2018, respectively.

Concentration of Significant Customers & Geographical Sales

After the Company sold its Cell Therapy business, BARDA accounted for 100% of our revenue from continuing operations which are recognized for year ended December 31, 2019 and 2018 and accounted for 100% of total outstanding accounts receivable presented in the accompanying consolidated financial statements.

Research and Development

Research and development expenditures, which are charged to operations in the period incurred, include costs associated with the design, development, testing and enhancement of the Company's products, regulatory fees, the purchase of laboratory supplies, and pre-clinical and clinical studies as well as salaries and benefits for our research and development employees.

Also included in research and development expenditures are costs incurred to support the government reimbursement contract, including $1.5 million and $2.7 million of qualified expenses that were incurred for the years ended December 31, 2019 and 2018, related to our government contract with BARDA.

Deferred Financing Costs and Other Debt-Related Costs

Deferred financing costs are capitalized, recorded as an offset to debt balances and amortized to interest expense over the term of the associated debt instrument using the effective interest method. If the maturity of the debt is accelerated because of default or early debt repayment, then the amortization would be accelerated.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income (loss) in the years in which those temporary differences are expected to be recovered or settled. Due to our history of losses, a full valuation allowance has been recognized against our deferred tax assets.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2019 and 2018, the Company has not recorded any interest or penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

Share-Based Compensation

The Company recognizes the fair value of all share-based payment awards in our statements of operations over the requisite vesting period of each award, which approximates the period during which the employee and non-employee director is required to provide service in exchange for the award. The Company estimates the fair value of these options using the Black-Scholes option pricing model using assumptions for expected volatility, expected term, and risk-free interest rate. Expected volatility is based primarily on historical volatility and is computed using daily pricing observations for recent periods that correspond to the expected term of the options. The expected term is calculated based on historical data for and applied to all employee awards as a single group as the Company does not expect (nor does historical data suggest) substantially different exercise or post-vesting termination behavior amongst our employee population. The risk-free interest rate is the interest rate for treasury instruments with maturities that approximate the expected term.

Segment Information

For the years ended December 31, 2019 and 2018, the Company is managed as a single operating segment, therefore we report our results in one operating segment.

Loss Per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential common shares were related entirely to outstanding but unexercised options, warrants and convertible preferred stocks for all periods presented.

The Company excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the years ended December 31, 2019 and 2018, as their inclusion would be antidilutive.

Recently Issued and Recently Adopted Accounting Pronouncements

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance is effective in the first quarter of 2023 for calendar-year SEC filers that are smaller reporting companies as of the one-time determination date. Early adoption is permitted beginning in 2019. The Company plans to adopt the new guidance on January 1, 2023, and it does not expect that adoption of this standard will have an impact on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In February 2017, the FASB issued ASU 2017-04, Simplifying the Test for Goodwill Impairment, to simplify how all entities assess goodwill for impairment by eliminating Step 2 from the goodwill impairment test. As amended, the goodwill impairment test will consist of one step comparing the fair value of a reporting unit with its carrying amount. An entity should recognize a goodwill impairment charge for the amount by which the reporting unit's carrying amount exceeds its fair value. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this ASU as of January 1, 2019 and the adopted did not have a material impact on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, *Leases*. Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. The Company adopted ASC 842 as of January 1, 2019, electing the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company elected the package of practical expedients permitted under the transition guidance. As a result of the adoption, the Company recorded right-of-use assets and liabilities. As of December 31, 2019, the Company's right-of-use assets and liabilities were $0.8 million associated with its operating leases.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which amends the FASB Accounting Standards Codification in order to simplify the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees will be aligned with the requirements for share-based payments granted to employees. The guidance mandates the modified retrospective approach and is effective for annual and interim reporting periods beginning after December 31, 2018, with early adoption permitted. The Company adopted this ASU as of January 1, 2019 and the adoption did not have an impact on the Company's consolidated financial statements.

3. Fair Value

Measurements

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the asset or liability. We follow a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

Warrants issued by the Company in connection with the 2018 Rights Offering in July 2018 (“Series T Warrants”) and in September 2019 Offering (“Series U Warrants”) are classified as liabilities instruments. Because some of the inputs to our valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

The Series T Warrants are not traded in an active securities market, and as such the estimated the fair value as of December 31, 2019 and 2018 was determined by using an option pricing model with the following assumptions:

	As of December 31, 2019	As of December 31, 2018
Expected term	1.1 years	2.1 years
Common stock market price	$ 2.40	$ 14.50
Risk-free interest rate	1.59%	2.48%
Expected volatility	168%	125%
Resulting fair value (per warrant)	$ 1.47	$ 6.50

The warrants issued in connection with the 2018 Rights Offering may be redeemed by the Company at $0.01 per warrant prior to their expiration if the Company’s common stock closes above $3.63 per share, subject to adjustment, for 20 consecutive trading days. The initial fair value of the liability associated with these warrants was $3.1 million, and the fair value decreased to $0.1 million as of December 31, 2019. The main driver for the change in the fair value of warrants at December 31, 2019 and 2018, was related to the change in our stock price.

The Company estimated the fair value of the Series U Warrants on the issuance date as well as at December 31, 2019 with the Black Scholes model. The Series U warrants will be marked to market as of each balance sheet date until they are exercised or upon expiration, with the changes in fair value recorded as non-operating income or loss in the statement of operations and comprehensive income (loss).

	As of December 31, 2019	As of September 25, 2019
Expected term	4.75 years	5 years
Common stock market price	$ 2.40	$ 3.42
Risk-free interest rate	1.68%	1.60%
Expected volatility	134.5%	134.9%
Resulting fair value (per warrant)	$ 1.94	$ 2.90

The following table summarizes the change in our Level 3 warrant liability value (in thousands):

	Years ended December 31,	
Warrant liability	2019	2018
Beginning balance	$ 916	$ 3,148
Issuance of warrants	10,214	—
Exercises	(794)	—
Change in fair value	(3,407)	(2,233)
Ending balance	$ 6,929	$ 916

Financial Instruments

Fair value information is disclosed about all financial instruments, whether or not recognized in the balance sheets, for which it is practicable to estimate fair value. The disclosures of estimated fair value of financial instruments at December 31, 2019 and 2018, were determined using available market information and appropriate valuation methods. Considerable judgment is necessary to interpret market data and develop estimated fair value. The use of different market assumptions or estimation methods may have a material effect on the estimated fair value amounts.

The carrying amounts for cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments.

At December 31, 2019 and 2018, the aggregate fair value and the carrying value of the Company's term loan were as follows (in thousands):

	December 31, 2019		December 31, 2018	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Debt	$ 10,761	$ 11,060	$ 14,043	$ 14,202

Carrying value is net of debt discount of $0.4 million and $0.6 million as of December 31, 2019 and 2018, respectively.

The fair value of debt is classified as Level 3 in the fair value hierarchy as some of the inputs, primarily the effective interest rate, to the valuation model are either not observable quoted prices or are not derived principally from or corroborated by observable market data by correlation or other means.

Nonfinancial Assets and Liabilities

The Company applies fair value techniques on a non-recurring basis, if and when necessary, associated with: (1) valuing potential impairment losses related to goodwill which are accounted for pursuant to the authoritative guidance for intangibles—goodwill and other; and (2) valuing potential impairment losses related to long-lived assets which are accounted for pursuant to the authoritative guidance for property, plant and equipment.

4. Discontinued Operations

As explained in Note 1, on April 24, 2019 and April 25, 2019, the Company completed the sale of its Cell Therapy business to Lorem and Mr. Shirahama. The following table summarizes the calculation of the loss on sale of the Cell Therapy business, which was finalized during the fourth quarter of 2019 (in thousands):

Consideration received	$ 7,000
Transaction costs	(1,363)
Net cash proceeds	5,637
Less:	
Carrying value of business and assets sold	12,145
Net loss on sale of business	$ (6,508)

There were no assets or liabilities related to discontinued operations as of December 31, 2019. Assets and liabilities related to discontinued operations or held for sale as of December 31, 2018 consisted of the following:

	December 31, 2018
Assets	
Current assets held for sale:	
Accounts receivable, net	$ 108
Inventory, net	2,841
Other current assets	328
	$ 3,277
Long-term assets held for sale:	
Property and equipment, net	260
Other noncurrent assets	1,866
Goodwill	3,550
Intangible assets, net	5,957
	11,633
Total assets	$ 14,910
Liabilities	
Current liabilities held for sale:	
Accounts payable and accrued liabilities	$ 580
Long-term liabilities held for sale:	
Other noncurrent liabilities	78
Deferred revenues	167
Noncurrent liabilities	$ 245
Total liabilities	$ 825

The following table summarizes the results of discontinued operations for the periods presented (in thousands).

	Year ended December 31,	
	2019	2018
Product revenue	$ 901	$ 2,671
License revenue	—	1,000
Total revenues	901	3,671
Cost of revenue	857	2,373
Gross profit	44	1,298
Operating expenses:		
Research and development	656	3,099
Sales and marketing	411	1,375
General and administrative	185	760
Total operating expenses	1,252	5,234
Operating loss	(1,208)	(3,936)
Other income (expense)	112	180
Loss from discontinued operations	$ (1,096)	$ (3,756)
Loss from sale of business	(6,508)	—
Net loss from discontinued operations	$ (7,604)	$ (3,756)

During the year ended December 31, 2019, revenues from discontinued operations were related to the Cell Therapy business. Because of the sale of the Cell Therapy business to Lorem and Mr. Shirahama, all product revenues and costs of product revenues for these periods have been recorded in loss from discontinued operations in the consolidated statements of operations.

Included in the statement of cash flows are the following non-cash adjustments related to the discontinued operations (in thousands):

	For the year ended December 31,	
	2019	2018
Depreciation and amortization	$ 467	$ 1,625
Provision for excess inventory	$ —	$ 463
Loss on asset disposal	$ —	$ (36)

5. Loss per Share

Net loss per share for year ended December 31, 2019 included a deemed dividend of $554,000 due to beneficial conversion feature recorded as a result of the adjustment of the conversion price of Series C Preferred Stock from $39.93 to $7.50 per share in August 2019. Net loss per share for year ended December 31, 2018 included a deemed dividend of $2.5 million to account for the beneficial conversion feature in connection with issuance of Series C Preferred Stock.

The following were excluded from the diluted loss per share calculation for the periods presented because their effect would be anti-dilutive:

	For the Year Ended December 31,	
	2019	2018
Outstanding stock options	1,865	3,000
Preferred stock	298,000	95,000
Outstanding warrants	3,637,000	178,000
Total	3,936,865	276,000

6. Composition of Certain Financial Statement Captions

Other Current Assets

As of December 31, 2019 and 2018, other current assets were comprised of the following (in thousands):

	December 31,	
	2019	2018
Prepaid services	$ 277	$ 166
Prepaid insurance	536	564
Other receivables	144	55
	$ 957	$ 785

Property and Equipment, net

As of December 31, 2019 and 2018, property and equipment, net, were comprised of the following (in thousands):

	December 31,	
	2019	2018
Office and computer equipment	$ 1,518	$ 1,279
Leasehold improvements	1,682	1,682
	3,200	2,961
Less accumulated depreciation	(1,021)	(662)
	$ 2,179	$ 2,299

Depreciation expense totaled $0.4 million and $0.3 million for the years ended December 31, 2019 and 2018, respectively.

Accounts Payable and Accrued Expenses

As of December 31, 2019 and 2018, accounts payable and accrued expenses were comprised of the following (in thousands):

	December 31,	
	2019	2018
Accrued expenses	$ 791	$ 824
Accounts payable	327	721
Accrued payroll and bonus	679	423
Accrued professional fees	332	186
Accrued vacation and compensation	166	192
Accrued R&D studies	858	230
Finance lease obligation - current	120	—
Other current liabilities	6	201
	$ 3,279	$ 2,777

7. Commitments and Contingencies

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company calculates the associated lease liability and corresponding right-of-use asset upon lease commencement using a discount rate based on the rate implicit in the lease or an incremental borrowing rate commensurate with the term of the lease.

The Company records lease liabilities within current liabilities or long-term liabilities based upon the length of time associated with the lease payments. The Company records its operating lease right-of-use assets as long-term assets. Right-of-use assets for financing leases are recorded within property and equipment, net in the Balance Sheet. Leases with an initial term of 12 months or less are not recorded on the Balance Sheet. Instead, the Company recognizes lease expense for these leases on a straight-line basis over the lease term. In connection with certain operating leases, the Company has security deposits recorded and maintained as restricted cash totaling $40 thousand as of December 31, 2019.

The Company leases laboratory, office and storage facilities in San Antonio, Texas, under operating lease agreements that expire in 2028. The Company also leases certain office space in Austin, Texas under a month-to-month operating lease agreement. In addition, the Company leases certain equipment under various operating and finance leases. The lease agreements generally provide for periodic rent increases, and renewal and termination options. The Company's lease agreements do not contain any material variable lease payments, residual value guarantees or material restrictive covenants.

Certain leases require the Company to pay taxes, insurance, and maintenance. Payments for the transfer of goods or services such as common area maintenance and utilities represent non-lease components. The Company elected the package of practical expedients and therefore does not separate non-lease components from lease components.

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets (in thousands, except years and rates):

	December 31, 2019
Assets	
Operating	$ 781
Financing	134
Total leased assets	$ 915
Liabilities	
Current:	
Operating	$ 147
Financing	120
Noncurrent:	
Operating	$ 646
Financing	8
Total lease liabilities	$ 921
Weighted-average remaining lease term (years) - operating leases	6.89
Weighted-average remaining lease term (years) - finance leases	1.08
Weighted-average discount rate - operating leases	7.93%
Weighted-average discount rate - finance leases	5.00%

The table below summarizes the Company's lease costs from its consolidated statements of operations, and cash payments from its consolidated statements of cash flows during year ended December 31, 2019.

	Year ended December 31, 2019
Lease expense:	
Operating lease expense	$ 225
Finance lease expense:	
Depreciation of right-of-use assets	116
Interest expense on lease liabilities	9
Total lease expense	$ 350
Cash payment information:	
Operating cash used for operating leases	$ 213
Financing cash used for financing leases	131
Total cash paid for amounts included in the measurement of lease liabilities	$ 344

Total rent expenses for the year ended December 31, 2019 was $0.7 million, which includes leases in the table above, month-to-month operating leases, and common area maintenance charges.

The Company's future minimum annual lease payments under operating and financing leases at December 31, 2019 are as follows (in thousands):

	Financing Leases	Operating Leases
2020	123	211
2021	7	183
2022	—	123
2023	—	100
Thereafter	—	447
Total minimum lease payments	$ 130	$ 1,064
Less: amount representing interest	(2)	(271)
Present value of obligations under leases	128	793
Less: current portion	(120)	(147)
Noncurrent lease obligations	$ 8	$ 646

Prior to December 2019, the Company also maintained office space for its former corporate headquarters in San Diego, California (the "Lease"). The initial term of the Lease is 63 months and may be extended upon mutual agreement. In connection with a restructuring announced in September 2017, the Company began negotiations with the landlord and in February 2018, announced a buy-out of its obligations with the Lease of approximately $0.6 million, included in the general and administrative expenses.

As of December 31, 2018, future minimum lease payments under the Company's lease obligations under ASC 840 were as follows:

Years Ending December 31,	Obligation
2019	$ 1,282
2020	638
2021	638
2022	192
Total	$ 2,750

Rent expenses, which includes common area maintenance, for the year ended December 31, 2018 was $1.9 million.

Other commitments

We have entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of December 31, 2019, we have clinical research study obligations of $0.9 million, which is expected to be paid within a year.

We are subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate.

On July 25, 2019, Tap Advisors LLC ("Tap") filed suit against the Company in the Supreme Court of the State of New York, County of New York, alleging the Company breached an agreement made in 2017, whereby Tap would provide certain financial advisory services to the Company. Tap sought to recover fees of approximately $3.7 million (plus attorneys' fees) that allegedly had not been paid by the Company related to the sale of its Cell Therapy business in April 2019. In December 2019, the Company settled the Tap litigation with cash payment of $0.7 million, which is included in the loss from discontinued operations for the year ended December 31, 2019.

8. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement, with Oxford (the "Loan and Security Agreement"), pursuant to which it funded an aggregate principal amount of $17.7 million ("Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, we were previously required to make interest only payments through June 1, 2016 and thereafter we were required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2019, the maturity date. On February 23, 2016, we received an acknowledgement and agreement from Oxford related to the positive data on our U.S. ACT-OA clinical trial. As a result, pursuant to the Loan and Security Agreement, the period for which we are required to make interest-only payments was extended from July 1, 2016 to January 1, 2017. All unpaid principal and interest with respect to the Term Loan was originally due and payable in full on June 1, 2019. The interest-only payment period and maturity date of the Term Loan were further amended as described in more details below. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, we are required to make a final payment in an aggregate amount equal to approximately $1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to Oxford warrants to purchase an aggregate of 188 shares of our common stock at an exercise price of $5,175 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt.

In September 2017 and June 2018, the Company entered into two amendments to the Term Loan which extended the interest-only period, and the Company agreed to pay Oxford an amendment fee of $250,000 at the earlier of maturity or acceleration of the loan.

On August 31, 2018, the Company entered into a third amendment (the "Third Amendment") to the Term Loan with Oxford. The Third Amendment extends the interest-only period under the Term Loan to December 31, 2018 and also requires that the Company pay to Oxford, in accordance with its pro rata share of the loans, 75% of all proceeds received (i) from the issuance and sale of unsecured subordinated convertible debt, (ii) in connection with a joint venture, collaboration or other partnering transaction, (iii) in connection with any licenses, (iv) from dividends (other than non-cash dividends from wholly owned subsidiaries) and (v) from the sale of any assets (such requirement, the "Prepayment Requirement"). The Prepayment Requirement does not apply to proceeds from the sale and issuance of the Company's equity securities, other than convertible debt. The Prepayment Requirement shall apply until an aggregate principle amount of $7.0 million has been paid pursuant to the Prepayment Requirement. However, if less than $7.0 million has been paid pursuant to the Prepayment Requirement on December 31, 2018 then the Company is required to promptly make additional payments until an aggregate principal amount of $7.0 million has been paid. The Company agreed to pay Oxford an amendment fee of $50,000 at the earlier of maturity or acceleration of the loan.

On December 31, 2018, the Company entered into a fourth amendment (the "Fourth Amendment") to the Term Loan with Oxford. Oxford agreed to extend the maturity date from June 1, 2019 to June 1, 2020. The Amendment increases the minimum liquidity covenant level from $1.5 million to $2.0 million and extends the interest-only period under the Loan Agreement to March 1, 2019. The Amendment also requires that the Company achieve one of the following by January 31, 2019: enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million; enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan Agreement would be paid down to a level satisfactory to Oxford. The Company agreed to pay Oxford an amendment fee of $350,000 at the earlier of maturity or acceleration of the loan.

On February 13, 2019, the Company entered into a fifth amendment of the loan agreement to primarily extend the January 31, 2019 obligations under the Fourth Amendment to February 28, 2019. On March 4, 2019, the Company entered into a sixth amendment of the loan agreement to primarily extend the February 13, 2019 obligations under the fifth amendment to March 29, 2019.

On April 29, 2019, the Company entered into a seventh amendment (the "Seventh Amendment") to the Term Loan, pursuant to which, among other things, Oxford agreed to interest only payments starting May 1, 2019, with amortization payments resuming on May 1, 2020. On July 15, 2019, the Company entered into an eighth amendment (the "Eighth Amendment") to the Term Loan primarily to obtain the consent from Oxford for its name change to Plus Therapeutics, Inc.

As described in more detail in Note 13, on March 29, 2020 the Company entered into a ninth amendment to the Loan and Security Agreement (the "Ninth Amendment").

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving certain liquidity levels when the total principal outstanding under the Loan Agreement is less than $3 million. As of December 31, 2019, we were in compliance with all of the debt covenants under the Loan and Security Agreement.

The Term Loan Agreement contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by us or a declaration of material adverse change by our lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Term Loan, which could materially harm our financial condition. As of December 31, 2019, we were in compliance with all covenants under the Term Loan and have not received any notification or indication from Oxford to invoke the material adverse change clause. However, due to our current cash flow position and the substantial doubt about our ability to continue as a going concern, the entire principal amount of the Term Loan has been reclassified to short-term. We will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should our financial condition improve.

Additional details relating to the outstanding Term Loan as of December 31, 2019 and 2018 are presented in the following table (in thousands):

Year ended December 31, 2019

Origination Date	Original Loan Amount	Interest Rate**	Current Monthly Payment***	Original Term	Remaining Principal (Face Value)
May 2015	$ 17,700	8.95%	$ 72	48 Months	$ 9,288

Year ended December 31, 2018

Origination Date	Original Loan Amount	Interest Rate**	Current Monthly Payment*	Original Term	Remaining Principal (Face Value)
May 2015	$ 17,700	8.95%	$ 100	48 Months	$ 12,980

* *Monthly payment as of December 2018, which reflects interest only*
** *3 month LIBOR rate with a floor of 1% plus 7.95%*
*** *Monthly payment as of December 2019, which reflects interest only*

As of December 31, 2019, the future contractual principal and final fee payments on all of our debt obligations are as follows (as thousands):

Years Ending December 31,	
2020	$ 5,308
2021	6,180
Total	$ 11,488

Reconciliation of Face Value to Book Value as of December 31, 2019	
Total debt obligations, including final payment fee (Face Value)	$ 11,488
Less: Debt discount	(428)
Total obligation	$ 11,060

Our interest expense for the years ended December 31, 2019 and 2018 was $1.9 million and $1.9 million, respectively. Interest expense is calculated using the effective interest method, therefore it is inclusive of non-cash amortization in the amount of $0.5 million and $0.6 million, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

9. Income Taxes

The Company has recorded a full valuation allowance against deferred tax assets and due to our net losses for the years ended December 31, 2019 and 2018, there was no provision or benefit for income taxes recorded.

The components of income/(loss) from continuing operations before income tax provision (benefit) as of December 31, 2019 and 2018 are as follows (in thousands):

	2019	2018
U.S.	$ (3,439)	$ (8,346)
Foreign	403	(507)
	$ (3,036)	$ (8,853)

A reconciliation of the total income tax provision tax rate to the statutory federal income tax rates of 21% for the years ended December 31, 2019 and 2018, respectively, is as follows:

	2019	2018
Income tax expense (benefit) at federal statutory rate	(21.0)%	(21.0)%
Income tax expense (benefit) at state statutory rate	(12.2)%	(6.1)%
Change in valuation allowance	23.0%	34.8%
Change in state rate	(1.3)%	(0.1)%
Permanent interest adjustments	1.1%	0.7%
Stock compensation	13.7%	1.8%
Research credit	(1.8)%	(1.4)%
Return to provision	3.1%	(3.4)%
NOLs expiring and adjustments to NOL	19.2%	—
Mark to market adjustment	(24.0)%	(5.3)%
Other, net	0.2%	—
	0.0%	(0.0)%

The tax effects of temporary differences that give rise to significant portions of our deferred tax assets and deferred tax liabilities as of December 31, 2019 and 2018 are as follows (in thousands):

	2019	2018
Deferred tax assets:		
Allowances and reserves	$ 6	$ 270
Accrued expenses	283	122
Stock based compensation	657	996
Net operating loss carryforwards	92,659	91,197
Income tax credit carryforwards	8,749	8,671
Property and equipment, principally due to differences in depreciation	95	548
Intangible assets	370	
Other, net	217	38
	103,036	101,842
Valuation allowance	(102,822)	(101,091)
Total deferred tax assets, net of allowance	214	751
Deferred tax liabilities:		
Other	(214)	(751)
Total deferred tax liability	(214)	(751)
Net deferred tax assets (liability)	$ —	$ —

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of $102.8 million as of December 31, 2019 as it does not believe it is more likely than not our net deferred tax assets will be realized. The Company increased its valuation allowance by approximately $1.7 million during the year ended December 31, 2019.

At December 31, 2019, we had federal, and state tax loss carry forwards of approximately $386.8 million, and $161.9 million, respectively. The federal and state net operating loss carry forwards begin to expire in 2020 and 2028, respectively, if unused. The federal net operating loss carryover includes $21.9 million of net operating losses generated in 2018. Federal net operating losses generated from 2018 onwards carryover indefinitely and may generally be used to offset up to 80% of future taxable income. At December 31, 2019, we had federal and state tax credit carry forwards of approximately $6.4 million and $5.5 million, respectively, after reduction for uncertain tax positions. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2020, if unused, and the state credits carry forward indefinitely.

Pursuant to the Internal Revenue Code ("IRC") of 1986, as amended, specifically IRC §382 and IRC §383, The Company's ability to use net operating loss and R&D tax credit carry forwards ("tax attribute carry forwards") to offset future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382 for taxable years ended after December 31, 2007. If ownership changes within the meaning of IRC Section 382 are identified as having occurred subsequent to 2007, the amount of remaining tax attribute carry forwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC §382.

The Company follows the provisions of income tax guidance which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company has not recognized any liability for uncertain tax positions as of December 31, 2019 and 2018.

Following is a tabular reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Unrecognized Tax Benefits – Beginning	$ 2,216	$ 2,157
Gross increases – tax positions in prior period	—	1
Gross decreases – tax positions in prior period	(18)	(3)
Gross increase – current-period tax positions	36	61
Unrecognized Tax Benefits – Ending	$ 2,234	$ 2,216

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal reduction in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

The Company did not recognize interest related to unrecognized tax benefits in interest expense and penalties in operating expenses as of December 31, 2019.

The Company's material tax jurisdictions are the United States and California. To its knowledge, the Company is currently not under examination by the Internal Revenue Service or any other taxing authority.

The Company's tax years for 2016 (federal) and 2015 (CA) remain open to examination by the taxing authority. While not open to examination, the tax attributes generated in tax years 1998 (federal) and 1997 (CA) and forward are subject to adjustment by the taxing authorities if utilized in tax years which are still open to examination.

10. Employee Benefit Plan

We implemented a 401(k) retirement savings and profit sharing plan (the "Plan") effective January 1, 1999. We may make discretionary annual contributions to the Plan, which is allocated to the profit sharing accounts based on the number of years of employee service and compensation. At the sole discretion of the Board of Directors, we may also match the participants' contributions to the Plan. We made no discretionary or matching contributions to the Plan in 2019 or 2018.

11. Stockholders' Equity

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock, par value $0.001 per share. The Company's Board of Directors is authorized to designate the terms and conditions of any preferred stock we issue without further action by the common stockholders. There were no shares of Series A 3.6% Convertible Preferred Stock outstanding as of December 31, 2019 and 2018. There were 1,021 and 1,112 shares of Series B Convertible Preferred Stock outstanding as of December 31, 2019 and December 31, 2018, respectively. There were 938 and 3,494 shares of Series C Preferred Stock outstanding as of December 31, 2019 and December 31, 2018, respectively.

On July 25, 2018, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value $0.001 per share, designated as the Series C Convertible Preferred Stock (the "Series C Preferred Stock"). The number of shares initially constituting the Series C Preferred Stock was set at 7,000 shares. Pursuant to a registration statement on Form S-1 originally filed on April 27, 2018, as amended, and became effective on July 17, 2018, and related prospectus (as supplemented), the Company registered and distributed to holders of its common stock and Series B Convertible Preferred Stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 20,000 units each consisting of one share of Series C Preferred Stock and 1,050 warrants for $1,000 per unit. Pursuant to the 2018 Rights Offering, which closed on July 25, 2018, the Company sold an aggregate of 6,723 units, resulting in total net proceeds to the Company of approximately $5.7 million. On August 2, 2019, in connection with a sale of common stock, the Company notified holders of the Company's Series C Preferred Stock that the conversion price of such stock was reduced from $39.93 to $7.50. The reduction of the effective conversion price of the Series C Preferred Stock resulted in a beneficial conversion feature recorded as a deemed dividend to the Series C Preferred Stock holders in the amount of $554,000. The deemed dividend is recorded as a reduction to loss available for common stockholder for basic and diluted loss per share calculation (Note 5). In addition, on August 2, 2019, the Company notified holders of the Company's Series T Warrants that the exercise price of such warrants was reduced from $0.7986 to $0.15, so that every 50 Series T warrants can be exercised into one share of common stock at $7.50. On September 25, 2019, in connection with the September 2019 Offering, the exercise price of the Series T Warrants was further adjusted such that every 50 warrants can be exercised into one share of common stock for $3.2132, and the conversion price of the Series C Preferred Stock was reduced from $7.50 to $3.2132.

As of December 31, 2019, there were 3,788,400 outstanding Series T Warrants which can be exercised into in aggregate 75,768 shares of common stock. In addition, there were 938 shares of Series C Preferred Stock that can be exercised into 291,920 shares of common stock.

The fair value of the common stock into which the Series C Preferred Stock was convertible on the date of issuance exceeded the proceeds allocated to the preferred stock, resulting in the beneficial conversion feature that we recognized as a deemed dividend to the preferred stockholders and, accordingly, an adjustment to net loss to arrive at net loss allocable to common stockholders. The Company recorded a deemed dividend within additional paid-in capital of $2.5 million for the year ended December 31, 2018, related to a beneficial conversion feature included in the issuance of our Series C Convertible Preferred Stock.

Common Stock

As mentioned in Note 1, the Company completed the September 2019 Offering. The Company issued 289,000 shares of its common stock, along with pre-funded warrants to purchase 2,711,000 shares of its common stock and Series U Warrants to purchase 3,450,000 shares of its common stock at $5.00 per share. By December 31, 2019, all pre-funded warrants have been exercised. The Series U Warrants remained outstanding as of December 31, 2019 and have a term of five years from the issuance date. In addition, the Company issued warrants to the Representatives to purchase 75,000 shares of its common stock at $6.25 per share with a term of 5.0 years from the issuance date, in the form of Series U Warrants.

In accordance with authoritative guidance, the pre-funded warrants are classified as equity. The Series U Warrants and the Representative Warrants are classified as liabilities due to a contingent obligation for the Company to settle the Series U Warrants with cash upon certain change in control events.

In accordance with authoritative guidance, the proceeds from the September 2019 Offering was allocated using the residual method, first to the Series U Warrants at the full fair value and the remainder to equity. The Series U Warrants and the Representative Warrants are revalued at each balance sheet date with change in fair value recorded as other income or loss in the statement of operations and comprehensive income (loss).

On June 1, 2018, the Company entered into a Sales Agreement with B. Riley FBR to sell shares of its common stock having an aggregate offering price of up to $6.5 million through its ATM program. Through December 31, 2018, the Company sold a total of 79,234 shares for proceeds of approximately $1.7 million through the ATM program.

On September 21, 2018, the Company entered into the Lincoln Park Purchase Agreement with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to $5.0 million of shares, of the Company's common stock, over the 24-month period following October 15, 2018. Through December 31, 2018, the Company sold a total of 12,802 shares for proceeds of approximately $0.3 million through the Lincoln Park Purchase Agreement. During the year ended December 31, 2019, 32,170 shares for proceeds of approximately $0.3 million were sold. The Company believes there is an insignificant amount remaining available under this financing facility as of December 31, 2019.

12. Stock-based Compensation

In August 2014, the Company adopted the 2014 Equity Incentive Plan (the "2014 Plan"), which provides its employees, directors and consultants the opportunity to purchase the Company's common stock in the form of options (incentive or non-qualified), stock appreciation rights, restricted stock purchase rights, restricted stock bonuses, restricted stock units, performance shares, performance units, cash-based awards other stock-based awards, and deferred compensation awards. The 2014 Plan initially provides for issuance of 530 shares of its common stock. In August 2015, the Company amended the 2014 Plan to add 603 shares to its share pool. In addition, the amendment increased the number of "incentive stock options" which may be issued under the 2014 Plan by an identical amount. In May 2016, May 2017 and May 2018, the Company amended the 2014 Plan to add 666, 4,000, and 15,000 shares, respectively, to its share pool. During 2019, the Company amended the 2014 Plan to add 80,000 shares to its share pool.

On December 29, 2015, the Company adopted the 2015 New Employee Incentive Plan (the "2015 Plan"). Awards under the 2015 Plan may only be made to an employee who has not previously been an employee or member of the Board of any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The 2015 Plan provides for issuance of 133 shares. In January 2017, the Company amended the 2015 Plan to add 500 shares to its share pool.

As of December 31, 2019, there are 30 shares and 99,699 shares of common stock remaining and available for future issuances under the 2015 and 2014 Plans, respectively, which are exclusive of securities to be issued upon an exercise of outstanding options, warrants, and rights.

In February 2020, the Company amended the 2015 Plan to increase the total number of shares of common stock reserved for issuance under the plan by 250,000 shares.

Stock Options

Generally, options issued under the 2014 Plan, are subject to four-year vesting, and have a contractual term of 10 years. Most options contain one of the following two vesting provisions:

- 12/48 of a granted award will vest after one year of service, while an additional 1/48 of the award will vest at the end of each month thereafter for 36 months, or
- 1/48 of the award will vest at the end of each month over a four-year period.

A summary of activity for the year ended December 31, 2019 and December 31, 2018 is as follows:

	Options	Weighted Average Exercise Price
Balance as of December 31, 2018	2,752	$ 4,003.50
Granted	2,800	$ 15.69
Expired	(37)	$ 41,692.00
Cancelled/forfeited	(3,650)	$ 1,089.35
Balance as of December 31, 2019	1,865	$ 2,968.22

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2019	1,865	$ 2,968.22	7.20	$ -
Vested and expected to vest at December 31, 2019	1,658	$ 3,286.28	7.10	$ -
Exercisable at December 31, 2019	1,133	$ 4,729.07	6.50	$ -

There were no stock options exercised in 2019 or 2018.

The fair value of each option awarded during the year ended December 31, 2019 and 2018 was estimated on the date of grant using the Black-Scholes-Merton option valuation model based on the following weighted-average assumptions:

	Years ended December 31,	
	2019	2018
Expected term	7.0 years	7.1 years
Risk-free interest rate	2.41%	2.94%
Volatility	96.52%	92.87%
Dividends	—	—
Resulting weighted average grant date fair value	$ 0.26	$ 1.74

The weighted average risk-free interest rate represents the interest rate for treasury constant maturity instruments published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, we use the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

The dividend yield has been assumed to be zero as the Company (a) has never declared or paid any dividends and (b) does not currently anticipate paying any cash dividends on its outstanding shares of common stock in the foreseeable future.

	Years ended December 31,	
	2019	2018
Total compensation cost for share-based payment arrangements recognized in the statement of operations (net of tax of $0)	$ 127	$ 355

As of December 31, 2019, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately $58,000, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.39 years.

To settle stock options, the Company issue new shares of our common stock. At December 31, 2019, the Company had an aggregate of 97,866 shares authorized and available to satisfy option exercises under its plans.

13. Subsequent Events

Term Loan Amendment

On March 29, 2020 the Company entered into the Ninth Amendment of the Loan and Security Agreement, pursuant to which, among other things, Oxford agreed to defer the start date of principal repayment from May 1, 2020 to May 1, 2021. In addition, the Company made a $5.0 million paydown of principal upon execution of the Ninth Amendment. As a result of this Ninth Amendment, the term of the Term Loan has been extended from June 1, 2021 to June 1, 2024, with all other major terms remaining consistent.

License Agreement

On March 29, 2020 the Company entered into an exclusive license agreement with NanoTx, Corp (“NanoTx”) for global development and commercialization of its glioblastoma treatment. Once certain post transaction requirements are met, the Company will make an initial license fee payment of $400,000 in cash and $300,000 in the Company’s common stock, based on a mutually agreed upon price consisting of the Company’s weighted average closing stock prices prior to the issuance of such shares of common stock. This license agreement commits the Company to certain milestone payments to NanoTx for successful completion of various milestones, together with royalty and sales payments based on the successful commercialization of the treatment.

Impact of Coronavirus Outbreak

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company's financial condition, liquidity, and future results of operations. Management is actively monitoring the impact of the global situation on its financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for fiscal year 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or furnished pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal accounting officer and principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report were effective.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our Board of Directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this Annual Report on Form 10-K based on the criteria set forth in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019 based on the COSO criteria.

This report does not include an attestation report on internal control over financial reporting by the Company's independent registered public accounting firm since the Company is a smaller reporting company under the rules of the SEC.

(c) Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be set forth under the captions “Election of Directors – Directors and Nominees,” “Executive Officers,” “Certain Relationships and Related Transactions – Section 16(a) Beneficial Ownership Reporting Compliance,” “Code of Business Conduct and Ethics” and “Corporate Governance – Board Committees” in our definitive proxy statement to be filed with the SEC, in connection with our 2020 annual meeting of stockholders (the “Proxy Statement”), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2019, and is incorporated in this report by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth under the captions “Executive Compensation”, “Corporate Governance — Compensation Committee Interlocks and Insider Participation,” “Corporate Governance – Compensation Committee Report” and “Corporate Governance — Non-Employee Director Compensation” in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation — Equity Compensation Plan Information” in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth under the captions “Certain Relationships and Related Person Transactions” and “Corporate Governance — Board Independence” in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth under the caption “Audit Matters — Principal Accounting Fees and Services” in the Proxy and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) (1) Financial Statements.

The responses to this portion of Item 15 are set forth under Part II, Item 8 above.

(a) (2) Financial Statement Schedules.

None.

(a) (3) Exhibits.

List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b) Exhibits.

The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

Item 16. Form 10-K Summary.

None.

EXHIBIT INDEX
PLUS THERAPEUTICS, INC.

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
2.1	Asset and Equity Purchase Agreement, dated as of March 29, 2019, by and among Cytori Therapeutics, Inc., Lorem Vascular Pte. Ltd., and with respect to Section 6.06 only, Cytori Therapeutics, K.K.		8-K	001-34375 Exhibit 2.1	04/01/2019
2.2	Asset and Share Sale and Purchase Agreement, dated as of April 19, 2019, by and among Cytori Therapeutics, Inc. and Seijirō Shirahama.		8-K	001-34375 Exhibit 2.1	04/23/2019
3.1	Composite Certificate of Incorporate		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	05/23/2018
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	08/06/2019
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation.		8-K	001-34375 Exhibit 3.1	07/29/2019
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock		8-K	001-34375 Exhibit 3.1	10/08/2014
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock		8-K	001-34375 Exhibit 3.1	11/28/2017
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.		8-K	001-34375 Exhibit 3.1	07/25/2018
3.8	Amended and Restated Bylaws of Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 3.2	07/29/2019
4.1	Description of Securities	X			
4.2	Form of Common Stock Certificate		10-K	001-34375 Exhibit 4.33	03/09/2018
4.3	Form of Series S Warrant.		S-1/A	333-219967 Exhibit 4.27	10/03/2017
4.4	Form of Series T Warrant.		POS AM	333-224502 Exhibit 4.28	07/09/2018
10.1+	Sale License Supply Agreement, dated July 30, 2013, by and between Plus Therapeutics, Inc. and Bimini Technologies LLC		10-Q/A	011-34375 Exhibit 10.93	2/12/2014
10.2+	Amended and Restated License and Supply Agreement, dated January 30, 2014, by and between Plus Therapeutics, Inc. and Lorem Vascular Pty. Ltd.		8-K	011-34375 Exhibit 10.94	02/04/2014
10.3+	Patent and Know-How License Agreement, dated March 29, 2020, by and between Plus Therapeutics, Inc. and NanoTx, Corp.		8-K	011-34375 Exhibit 10.1	3/30/2020
10.4	Registration Rights Agreement between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated September 21, 2018.		8-K	001-34375 Exhibit 10.2	09/21/2018
10.5	Registration Rights Agreement between Plus Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated December 22, 2016.		8-K	001-34375 Exhibit 10.2	12/29/2016
10.6	Common Stock Purchase Agreement, dated February 8, 2008, by and between Green Hospital Supply, Inc. and Plus Therapeutics, Inc.		8-K	000-32501 Exhibit 10.51	2/19/2008

10.7	Common Stock Purchase Agreement, dated December 6, 2010, by and among Plus Therapeutics, Inc. and Astellas Pharma Inc.		8-K	001-34375 Exhibit 10.76	12/09/2010
10.8+	Asset Purchase Agreement by and between Plus Therapeutics, Inc. and Azaya Therapeutics, Inc., effective January 16, 2017.		10-K	001-34375 Exhibit 10.40	03/24/2017
10.9	Loan and Security Agreement, dated May 29, 2015, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-Q	001-34375 Exhibit 10.4	08/10/2015
10.10	First Amendment to Loan and Security Agreement, dated September 20, 2017, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		S-1/A	333-219967 Exhibit 10.45	10/03/2017
10.11	Second Amendment to Loan and Security Agreement, dated June 19, 2018, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-Q	001-34375 Exhibit 10.3	08/14/2018
10.12	Third Amendment to Loan and Security Agreement, dated August 31, 2018, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		S-1	333-227485 Exhibit 10.51	09/21/2018
10.13	Fourth Amendment to Loan and Security Agreement dated December 31, 2018, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		S-1	333-229485 Exhibit 10.52	02/01/2019
10.14	Fifth Amendment to Loan and Security Agreement dated February 13, 2019, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-K	001-34375 Exhibit 10.55	03/29/2019
10.15	Sixth Amendment to Loan and Security Agreement dated March 4, 2019, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-K	001-34375 Exhibit 10.56	03/29/2019
10.16	Seventh Amendment to Loan and Security Agreement dated April 24, 2019, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-Q	001-34375 Exhibit 10.3	05/14/2019
10.17	Eight Amendment to Loan and Security Agreement dated July 15, 2019, by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		10-Q	001-34375 Exhibit 10.2	08/15/2019
10.18+	Ninth Amendment to Loan and Security Agreement, dated March 29, 2020 by and between Plus Therapeutics, Inc. and Oxford Finance, LLC.		8-K	011-34375 Exhibit 10.2	3/30/2020
10.19#	Employment Agreement between Marc Hedrick and Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 10.1	3/12/2020
10.20#	Employment Agreement between Andrew Sims and Plus Therapeutics, Inc.		8-K	001-34375 Exhibit 10.2	3/12/2020
10.21#	2014 Equity Incentive Plan of Plus Therapeutics, Inc., as amended and restated.		10-Q	001-34375 Exhibit 10.3	08/15/2019
10.22#	Third Amendment to the Plus Therapeutics, Inc. 2014 Equity Incentive Plan, dated January 26, 2017.		10-K	001-34375 Exhibit 10.39	03/24/2017
10.23#	2015 New Employee Incentive Plan.		8-K	001-34375 Exhibit 10.1	01/05/2016
10.24#	First Amendment to the Plus Therapeutics, Inc. 2015 New Employee Incentive Plan, dated Jan. 26, 2017.		10-K	001-34375 Exhibit 10.42	03/24/2017
10.25#	Second Amendment to the Plus Therapeutics, Inc. 2015 New Employee Incentive Plan, dated February 6, 2020.	X			
10.26#	Form of Notice of Grant of Stock Option under the 2015 New Employee Incentive Plan.		S-8	333-210211 Exhibit 99.5	03/15/2016

10.27#	Form of Stock Option Agreement under the 2015 New Employee Incentive Plan.		S-8	333-210211 Exhibit 99.4	03/15/2016
10.28#	Form Indemnification Agreement		8-K	001-34375 Exhibit 10.1	02/06/2020
10.29#	Form of Agreement for Acceleration and/or Severance.		10-K	001-34375 Exhibit 10.113	03/11/2016
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.	X			
24.1	Power of Attorney (see signature page).	X			
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes -Oxley Act of 2002.	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Schema Document	X			
101.CAL	XBRL Calculation Linkbase Document	X			
101.DEF	XBRL Definition Linkbase Document	X			
101.LAB	XBRL Label Linkbase Document	X			
101.PRE	XBRL Presentation Linkbase Document	X			

 # Indicates management contract or compensatory plan or arrangement.

+ Portions of this exhibit have been omitted and provided separately to the SEC pursuant to a request for confidentiality treatment

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, MD
Marc. H. Hedrick, MD
President & Chief Executive Officer
March 30, 2020

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew Sims and Desiree Smith, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place, or stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, 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 to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Richard J. Hawkins Richard J. Hawkins	*Chairman of the Board*	March 30, 2020
/s/ Marc H. Hedrick, MD Marc H. Hedrick, MD	*President & Chief Executive Officer (Principal Executive Officer)*	March 30, 2020
/s/ Andrew Sims Andrew Sims	*Chief Financial Officer and VP of Finance (Principal Financial and Accounting Officer)*	March 30, 2020
/s/ An van Es-Johansson, MD An van Es-Johansson, MD	*Director*	March 30, 2020
/s/ Greg Petersen Greg Petersen	*Director*	March 30, 2020

Exhibit 4.1

DESCRIPTION OF THE COMPANY'S SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT OF 1934

The summary of general terms and provisions of the capital stock of Plus Therapeutics, Inc. (the "Company") set forth below does not purport to be complete and is subject to and qualified by reference to the Company's Amended and Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") and Amended and Restated Bylaws (as amended, the "Bylaws," and together with the Certificate of Incorporation, the "Charter Documents"), each of which is included as an exhibit to the Company's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and incorporated by reference herein. For additional information, please read the Charter Documents and the applicable provisions of the Delaware General Corporation Law (the "DGCL").

Authorized Capital Stock

The Company is authorized to issue up to 105,000,000 shares, of which (i) 100,000,000 have been designated common stock, par value $0.001 per share ("Common Stock"), and (ii) 5,000,000 have been designated preferred stock, par value $0.001 per share ("Preferred Stock").

Common Stock

Voting Rights

The holders of Common Stock possess exclusive voting rights in us, except to the extent our board of directors (the "Board") specifies voting power with respect to any other class of securities issued in the future. Each holder of our Common Stock is entitled to one vote for each share held of record on each matter submitted to a vote of stockholders, including the election of directors. Stockholders do not have any right to cumulate votes in the election of directors.

When a quorum is present at any meeting, the vote of the holders of a majority of the voting power of the Common Stock and entitled to vote present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which by express provision of the Charter Documents or by law, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors are elected by a plurality of the voting power of the shares present in person or represented by proxy and entitled to vote on the election of directors at a meeting at which a quorum is present, and stockholders are not entitled to cumulate their votes for the election of directors.

Dividend Rights

Subject to preferences that may be granted to the holders Preferred Stock, each holder of Common Stock is entitled to share ratably in distributions to stockholders and to receive ratably such dividends as may be declared by the Board out of funds legally available therefor.

No Preemptive or Similar Rights

Holders of Common Stock have no conversion, exchange, sinking fund, redemption or appraisal rights (other than such as may be determined by the Board in its sole discretion) and have no preemptive rights to subscribe for any of our securities.

Right to Receive Liquidation Distributions

In the event of our liquidation, dissolution or winding up, the holders of Common Stock will be entitled to receive, after payment of all of our debts and liabilities and of all sums to which holders of any Preferred Stock may be entitled, the distribution of any of our remaining assets.

Anti-Takeover Provisions in Charter Documents

Certain provisions of Charter Documents, which are summarized below, may have the effect of delaying, deferring or preventing another person from acquiring control of the Company. These provisions may discourage takeovers, coercive or otherwise, and are also designed, in part, to encourage persons seeking to acquire control of the Company to negotiate first with the Board. We believes that the benefits of increased protection of the our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire the Company because negotiation of these proposals could result in an improvement of their terms. These provisions include the following:

Board Vacancies. Our Bylaws provide that any vacancy or vacancies in the Board shall be deemed to exist in the case of the death, resignation or removal of any director, or if the authorized number of directors be increased. Vacancies may be filled by a majority of the remaining directors, though less than a quorum, or by a sole remaining director, unless otherwise provided in our Certificate of Incorporation, as amended. The stockholders may elect a director or directors at any time to fill any vacancy or vacancies not filled by the directors.

Stockholder Action; Special Meeting of Stockholders. Pursuant to Section 228 of the DGCL, any action required to be taken at any annual or special meeting of the stockholders may be taken without a meeting, without prior notice and without a vote if a consent or consents in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of stock entitled to vote thereon were present and voted, unless the Certificate of Incorporation provides otherwise. The Certificate of Incorporation provides that stockholders may not take action by written consent but may only take action at annual or special meetings of stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of stockholders called in accordance with the Bylaws. The Bylaws provides that special meetings of the stockholders may be called only at the request of our president, chief executive officer or chairman of the Board or by a majority of the Board. These provisions might delay the ability of the our stockholders to force consideration of a proposal or for stockholders controlling a majority of the our capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. The Bylaws provide advance notice procedures for 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. The Bylaws specify certain requirements regarding the form and content of a stockholder's notice and prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting. These provisions might preclude stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

No Cumulative Voting. The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our amended and restated of incorporation, as amended, provides otherwise. Our Charter Documents do not provide for cumulative voting.

Amendment of Charter Provisions and Bylaws. The Charter Documents provides that the Bylaws may be adopted, amended, altered or repealed by a vote of a majority of the total number of directors of the Board.

Issuance of Undesignated Preferred Stock. The authority possessed the Board to issue Preferred Stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest or otherwise by making such attempts more difficult or more costly. The Board may issue Preferred Stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of Common Stock.

Authorized but Unissued Shares. Our authorized but unissued shares of Common Stock and Preferred Stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of 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.

Business Combinations with Interested Stockholders. We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination, such as a merger, with an interested stockholder (i.e., subject to certain exceptions, a person or group owning 15% or more of the corporation's voting stock) for a period of three years following the date the person became an interested stockholder, unless (with certain exceptions) the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner.

Listing

The Common Stock is listed on the Nasdaq under the symbol "PSTV."

Exhibit 10.25

SECOND AMENDMENT TO
THE PLUS THERAPEUTICS, INC.
2015 NEW EMPLOYEE INCENTIVE PLAN

February 6, 2020

This Second Amendment amends the 2015 New Employee Incentive Plan (as amended, the "**Plan**") of Plus Therapeutics, Inc., a Delaware corporation (the "**Company**"). Unless otherwise specifically defined herein, each capitalized term used herein shall have the meaning afforded such term under the Plan.

WHEREAS, by unanimous written consent of the Board of Directors of the Company (the "**Board**"), effective February 6, 2020, the Board determined it to be in the best interests of the Company to amend the Plan to increase the number of shares of Stock authorized for issuance thereunder by 250,000 shares of Stock:

NOW, THEREFORE, be it resolved that the Plan is hereby amended as follows:

1. Share Limit. Section 4.1 of the Plan shall be amended by replacing it with the following:

"**Maximum Number of Shares Issuable**. Subject to adjustment as provided in Sections 4.2 and 4.3, the maximum aggregate number of shares of Stock that may be issued under the Plan pursuant to Awards shall be equal to 250,030 shares and shall consist of authorized but unissued or reacquired shares of Stock or any combination thereof."

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick
Name: Marc H. Hedrick, M.D.
Title: President and Chief Executive Officer

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Plus Therapeutics, Inc.
Austin, Texas

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-1 (Nos. 333-229485, 333-227485, 333-226205, 333-224502, 333-219967, 333-215365, and 333-210628), Forms S-3 (Nos. 333-217988, 333-172787, 333-169822, 333-157023, 333-140875, 333-134129, 333-153233, 333-159912, 333-192409, 333-200090, 333-195846, and 333-216947) and Forms S-8 (Nos. 333-223566, 333-210211, 333-202858, 333-181764, 333-122691 and 333-82074) of Plus Therapeutics, Inc. (formerly Cytori Therapeutics, Inc.) (the "Company") of our report dated March 30, 2020, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California

March 30, 2020

EXHIBIT 31.1

Certification of Principal Executive Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Marc H. Hedrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Plus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020
/s/ Marc H. Hedrick, MD
Marc. H. Hedrick,
President & Chief Executive Officer

EXHIBIT 31.2

Certification of Principal Financial Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Andrew Sims, certify that:

1. I have reviewed this Annual Report on Form 10-K of Plus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2020
/s/ Andrew Sims
Andrew Sims
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Plus Therapeutics, Inc. for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on March xx, 2020, (the "Report"), Marc H. Hedrick, as President & Chief Executive Officer of Plus Therapeutics, Inc., and Andrew Sims, as Chief Financial Officer of Plus Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Plus Therapeutics, Inc.

By: /s/ Marc H. Hedrick, MD
Marc H. Hedrick, MD
President & Chief Executive Officer

Dated: March 30, 2020

By: /s/ Andrew Sims
Andrew Sims
Chief Financial Officer

Dated: March 30, 2020