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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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

For the transition period from _____to _____

Commission file number 001-37568

PDS Biotechnology Corporation

(Exact name of registrant as specified in its charter)

Delaware	**26-4231384**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

303A College Road East, Princeton, NJ 08540
(Address of principal executive offices)

(800) 208-3343
(Registrant's telephone number)

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 $0.00033 per share	PDSB	Nasdaq Capital Market

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller Reporting Company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Yes ☒ No ☐

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 voting and non-voting common equity held by non-affiliates (without admitting that any person whose shares are not included in such calculation is an affiliate) of the registrant on the last day of the registrant's second fiscal quarter, was $18.1 million (based on the closing price for shares of the registrant's common stock as reported on the Nasdaq Capital Market on that date).

The number of shares of the registrant's common stock, par value $0.00033 per share, outstanding as of March 9, 2020 was $15,285,205.

Documents Incorporated By Reference

Portions of registrant's proxy statement relating to registrant's 2020 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the close of the registrant's fiscal year, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

PDS BIOTECHNOLOGY CORPORATION

FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2019

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" contained in Item 1A of this Annual Report. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Annual Report and you should not place undue reliance on these forward-looking statements.

These forward-looking statements include, but are not limited to, statements about:

- the accuracy of estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- our ability to obtain funding for our operations in the event we determine to raise additional capital;
- our ability to retain key management personnel;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our ability to maintain our listing on the Nasdaq Stock Market;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"); and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

In this Annual Report, unless otherwise stated or the context otherwise indicates, references to "PDS," "the Company," "we," "us," "our" and similar references refer to PDS Biotechnology Corporation, a Delaware corporation.

PART I

ITEM 1. Business

Company Overview

We are a clinical-stage biopharmaceutical company developing a new generation of multi- functional cancer immunotherapies. All PDS products are based on the proprietary Versamune® platform. Versamune® based cancer therapies are designed to stimulate disease-specific killer and helper T-Cell response in a quantity and quality that significantly surpasses current immunotherapeutic approaches. We believe that the Versamune® platform has the potential to rapidly become an industry-leading immuno-oncology technology and is currently being applied to the development of a robust pipeline of valuable new-generation, of advanced treatments for cancer as part of combination therapies and to help make standard of care therapies more effective.

Versamune® has been developed to encompass the attributes of the most successful immunotherapy approaches, such as checkpoint inhibitors, CAR-T cells and live-vector based vaccines, while also overcoming their limitations and potential negative side effects. It is well documented that the most critical attribute of an effective cancer immunotherapy is the induction of high levels of active antigen-specific CD8+ (killer) T-cells. Priming adequate levels of active CD8+ T-cells in-vivo continues to be a major obstacle facing immunotherapy. Our lead product PDS0101 (Versamune®+HPV antigens), is designed to address advanced HPV-associated cancers in its first human clinical trial, confirmed the impressive preclinical study results and demonstrated the unique in-vivo induction of high levels of active HPV-specific CD8+ T-cells in humans.

The unique combination of high potency and excellent safety of the Versamune® platform observed in preclinical studies appears to be corroborated in a successfully completed 12-patient Phase 1 clinical trial. In June 2019 the Versamune mechanism of action was published in one of the top peer reviewed journals in the field of immunology, (*Journal of Immunology*, 2019(202), 1215). The article describes the way PDS' Versamune platform recruits and activates killer T-cells to recognize and effectively attack cancer cells while simultaneously making cancer cells more susceptible to T-cell attack. With respect to our lead therapeutic candidate, PDS0101 (a combination of Versamune® nanoparticles plus proprietary human papillomavirus (HPV)-16 E6 and E7 antigens), the Journal of Immunology article detailed Versamune®'s ability to overcome the critical mechanisms associated with ineffective immune responses mediated by HPV16 and cancer cells, therefore leading to a superior anti-tumor effect.

The Phase 1 human trial immune responses mirrored the strong reported T-cell responses seen in preclinical studies, which led to superior anti-tumor regression efficacy in pre-clinical head-to-head studies with leading clinical development-stage technologies. In a retrospective analysis not contemplated in the initial study design, it was observed that 6 out of 10 evaluable patients experienced complete regression of their pre-cancerous lesions as early as 1-3 months after treatment, despite the fact that the HPV16 specific therapy was used on patients who were co-infected with multiple strains of the HPV virus. No lesion recurrence occurred within the 2 -year evaluation period.

We believe that the rational design of combination immunotherapies using agents that promote synergy with each other and reduce potential for compounded toxicity will substantially improve potential for combination therapies to deliver improved clinical benefit for cancer patients. Versamune® appears to activate the appropriate combination of immunological pathways that promote strong CD8+ T-cell induction, while also altering the tumor's microenvironment to make the tumor more susceptible to T-cell attack, which PDS believes makes it an ideal complement to the checkpoint inhibitors by enhancing their potency. In addition, the differences in mechanism of action between Versamune® and checkpoint inhibitors, as well as the initial demonstrated safety profile of Versamune®, suggests that these combinations may be much better tolerated by patients than many or most other combination therapies involving checkpoint inhibitors.

We expect substantial value accretion as our development-stage products successfully progress through upcoming human Phase 2 clinical studies. Initially, PDS intends to demonstrate the application of the Versamune® platform's attributes by progression in areas of high unmet medical need supported by leaders in the field. Our current clinical development plan for PDS0101 is summarized in the table below. All studies are expected to be initiated in the first half of 2020.

PDS Biotech Product	Indication	Partner	Combination Product	Study Size
PDS0101 (HPV16)	First line treatment of recurrent/metastatic head and neck cancer	MERCK	KEYTRUDA® (Standard of care)	96 subjects 20 US sites
	Advanced HPV-associated malignancies	NIH NATIONAL CANCER INSTITUTE	EMD Serono's M7824 and NHS-IL12	29 subjects 1 US site (NCI)
	Advanced, localized cervical cancer (Stage IIb-IVa)	Leading Cancer Research Institute: TBA	Chemo-radiation (Standard of care)	35 subjects 1 US site

Our pipeline of Versamune® based products is summarized below. With additional financing, we plan to initiate clinical studies with PDS0102 (TARP-expressing cancers, e.g. prostate and breast cancers), PDS0103 (MUC-1 expressing cancers, e.g. colon, breast, lung and ovarian cancers) and PDS0104 (TRP2 expressing cancers, e.g. melanoma).

Product	Indication	Partner	Combination	Status
PDS0102 (TARP)	Prostate and breast cancers	No industry partner selected	Checkpoint Inhibitor	Preclinical studies ongoing
PDS0103 (MUC-1)	Ovarian, colorectal, lung, breast cancers	No industry partner selected	Checkpoint Inhibitor	Preclinical studies ongoing
PDS0104 (Melanoma)	Melanoma	No industry partner selected	Checkpoint Inhibitor	Preclinical studies ongoing

Corporate Information

We currently operate the existing business of Private PDS (as defined below) as a publicly traded company under the name PDS Biotechnology Corporation (PDSB). We were incorporated as Edge Therapeutics, Inc., or Edge, on January 22, 2009. Upon closing of the Merger (as defined below), we suspended Edge's prior business and prioritized the business of PDS Biotechnology Corporation, a privately held Delaware corporation, which we refer to as Private PDS, which is a clinical-stage biopharmaceutical company developing multi-functional cancer immunotherapies that are designed to overcome the limitations of the current approaches.

On March 15, 2019, we completed our previously disclosed reverse merger with privately-held Private PDS, which we refer to as the Merger, pursuant to and in accordance with the terms of the Agreement and Plan of Merger, dated as of November 23, 2018, as amended on January 24, 2019, by and among Edge, Echos Merger Sub, a wholly-owned subsidiary of Edge, which we refer to as Merger Sub, and Private PDS, whereby Private PDS merged with and into Merger Sub, with Private PDS surviving as our wholly-owned subsidiary. In connection with and immediately following completion of the Merger, we effected a 1-for-20 reverse stock split, or the Reverse Stock Split, and changed our corporate name from Edge Therapeutics, Inc. to PDS Biotechnology Corporation, and Private PDS changed its name to PDS Operating Corporation. All of the outstanding stock of Private PDS was converted into shares of our common stock or canceled upon closing of the Merger. Unless otherwise stated, all share and per share numbers in this Annual Report on Form 10-K give retroactive effect to both the Merger and the Reverse Stock Split.

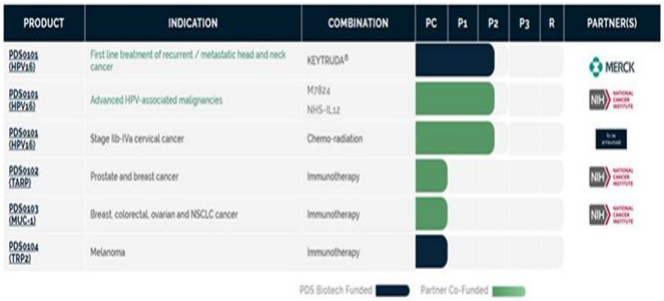
Since our inception in 2005, we have devoted substantially all of our resources to developing our Versamune® platform, advancing preclinical programs, conducting clinical studies, manufacturing PDS0101 for clinical studies, and providing general and administrative support. We have funded our operations primarily from the issuance of common stock. We have not generated any product revenue.

We acquired an in-process research and development asset relating to Edge's NEWTON 2 trials. Following the discontinuation of the NEWTON 2 trial for EG-1962, Edge had ceased all research and development efforts related to EG-1962 and suspended efforts on other legacy Edge product candidates. As of December 31, 2019, we are no longer seeking partners to continue the development of these product candidates and pursue them to commercialization.

Our principal executive offices are located 303A College Road East, Princeton, NJ 08540, and our telephone number is (800) 208-3343.

Commercial Strategy

Our mission is to apply the Versamune ® platform, our proprietary and versatile immunotherapy technology, to develop a new generation of immuno-oncology products that are effective and safe across a broad range of cancer types. Our current development pipeline of cancer immunotherapy products is based on the Versamune® platform, and can potentially be used as a component of combination products with other leading technologies to provide effective treatments across a range of cancer types, including Human Papillomavirus (HPV)-based cancers, melanoma, colorectal, lung, breast and prostate cancers or as monotherapies in early-stage disease.



Key elements of PDS's clinical and commercial execution strategy are as follows:

1. Rapidly progress our lead product candidate, PDS0101 into three proof-of-concept phase 2 human clinical studies. In the first trial PDS0101 is being studied in combination with KEYTRUDA® (standard of care) as first line treatment of recurrent or metastatic head and neck cancer. In the second trial to treat advanced HPV related cancers, PDS0101 is being studied in combination with two novel immunotherapies , EMD Serono's M7824 and NHS-IL12, in collaboration with the National Cancer Institute. In the third trial to treat advanced localized cervical cancer PDS0101 is being studied in combination with chemo-radiotherapy (standard of care);

2. Build our Versamune®-based immune-oncology pipeline, by continuing development of the PDS0102, 0103, and 0104 programs in prostate, breast, colorectal, lung, ovarian cancers and melanoma;

3. Commercialize our wholly-owned product candidates, including PDS0101, if approved, through partnerships or through a targeted sales force in the United States, Canada and Europe and with potential strategic partnerships outside of these regions; and

4. Continue to seek to maintain high barriers to entry around our product candidates and the markets in which they are utilized by using our composition of matter application patents as well as know how around our Versamune® platform technology.

Commercialization of Product Candidates

PDS retains worldwide rights to all of our product candidates. If our product candidates are approved, we intend to establish targeted commercialization and marketing capabilities for our products in the United States, Canada and Europe by developing a sales force that would focus on academic medical centers and large oncology clinics. For commercialization outside of the United States, Canada and Europe, we generally expect to enter into collaborations with strategic partners

Cancer Immunotherapy

In the field of cancer immunotherapy, a well-documented and significant unmet need is the ability of therapies to safely induce in vivo an adequate number of highly active/polyfunctional CD8+ T-cells, coupled with the altering of the tumor microenvironment in order to limit its immune tolerance, in order to facilitate efficient tumor cell killing. Our data to date suggests that the Versamune® platform effectively promotes both critical immunotherapeutic characteristics, leading to strong antigen-specific CD8+ T-cell induction and regression of lesions in a human clinical trial.

One of the most active areas of clinical testing in the field of cancer immunotherapy today is combining checkpoint inhibitors with other anti-cancer agents, with the goal of synergistic and thus superior and thus superior clinical efficacy compared with that of the individual products. We believe that next generation of combination immunotherapy agents, especially those including both checkpoint inhibitors and a second therapeutic agent, will need to have at least the following characteristics to achieve clinical and commercial success:

1. In vivo induction of high levels of tumor infiltrating CD8+ T-cells;

2. Further alteration of the tumor microenvironment through activation of complimentary immunological mechanisms; and

3. Lack of substantially higher combined toxicity than either component alone, in order to contribute a viable clinical application to cancer patients.

We believe based upon our research that Versamune®-based products fulfill each of these criteria.

Most immunotherapies work by training or priming our T-cells to recognize specific disease-related proteins (cancer, bacterial or viral) displayed or expressed by diseased cells. The ultimate goal of immunotherapy treatment is to harness the power of the immune system to target and kill specific diseased cells, and thereby cure the underlying disease.

Immunotherapies have recently been recognized as having significant potential to treat a broad range of cancers and infectious diseases. Several cancer immunotherapies have now been approved by the FDA, and other promising immunotherapy technologies and products are in various stages of advanced clinical development.

Despite the promise demonstrated by current immunotherapy technologies, these products still face significant hurdles to achieving optimal therapeutic value. Some key obstacles faced by the current technologies are the following:

Antigen Uptake by Dendritic Cells: Antigens are particular proteins recognizable by the immune system that are uniquely or highly expressed/present in tumor cells but not present in normal healthy cells. The first critical step in generating an effective antigen-specific or antigen-targeting T-cell response is efficient uptake of the particular antigens by dendritic cells, which are the key antigen presenting cells of the immune system. Proteins and peptides are not naturally highly taken up by dendritic cells, creating obstacles to effective T-cell response in existing immunotherapies. Versamune® has demonstrated the ability to promote antigen uptake by dendritic cells in-vivo.

Antigen Cross-Presentation and Killer (CD8+) T-Cell Priming: Suboptimal ability of the dendritic cells to internalize, process/break-down and present tumor antigens to the T-cells leads to ineffective activation or "priming" of killer T-cells. Dendritic cells are required to take up and process tumor antigens. These processed antigens must then enter into an internal compartment of the cell, called the cytoplasm. The peptide's presence in the cytoplasm is necessary to allow smaller processed proteins (peptides) to be presented to killer T-cells via what is known as the Major Histocompatibility Complex ("MHC") Class I pathway or to helper T-cells via the MHC Class II pathway. This is the process of T-cell priming. Current technologies have presented limited ability to adequately facilitate antigen presentation via the MHC Class I process *in vivo*, therefore leading sub-optimal killer T-cell priming and then weaker-than-optimal anti-tumor potency. Versamune ® has demonstrated the ability to promote antigen processing and presentation via MHC Class I and Class II leading to effective CD8+ and CD4+ T-cell priming respectively (*Ghandapudhi et al, J. Immunology, June 15, 2019, 202 (12) 3524-3536*). T-cell priming trains the killer T-cells to effectively identify the tumor cells.

Immune Activation: Once T-cell priming has successfully occurred, a subsequent critical step is induction-specific immunological signals, including induction of certain chemokines and cytokines necessary for activation and proliferation of various classes of T-cells. Chemokines and cytokines are each a broad category of immunological proteins that are crucial for fighting off infections and other immune responses. Versamune® has demonstrated the ability to specifically activate the important type I interferon signaling pathway, leading to induction of the right phenotype of active CD8+ T-cells with potent killing function (*Ghandapudhi et al, J. Immunology, June 15, 2019, 202 (12) 3524-3536*).

Overcoming Immune Suppression: A number of immune-suppressive mechanisms and cells naturally exist in humans that can increase in number within tumors. This may result in an inhibition of the ability of killer and helper T-cells to identify and kill the tumor cells. This state of immune tolerance must generally be overcome for T-cells to be effective in killing antigen-expressing cancer cells. In preclinical studies, Versamune® was demonstrated to alter the tumor micro-environment, making the tumors more susceptible to attack by T-cells (*Ghandapudhi et al, J. Immunology, June 15, 2019, 202 (12) 3524-3536*).

Complexity and Costs: The relatively high formulation and manufacturing complexities, as well as related high costs, associated with most commercially available immunotherapies is well documented. For example, live vector-based cancer vaccines and dendritic cell vaccines require complex and expensive processes to enable manufacturing of live agent (virus or bacteria)-based products. Versamune® is based on synthetic positively charged lipids, and traditional lipid nanoparticle manufacturing methods which results in a much simpler and less expensive manufacturing process than most other immunotherapy technologies.

Versamune® - A Next Generation Immunotherapy and Cancer Immunotherapy

Based on the limitations of current therapies described above, we believe that next generation biologics that can overcome those limitations are likely to address significant unmet needs. Versamune®, a T-cell activating platform technology, has demonstrated potential to overcome the challenges of immune therapy as illustrated below:

Versamune® Platform

Versamune® has been rationally designed and is based on synthetic positively charged (cationic) lipids. The structure of these lipids leads to spontaneous formation of nanoparticles in an aqueous medium. The nanoparticles are sized to promote efficient uptake by the antigen presenting cells of the immune system, the dendritic cells. The nanoparticles are combined with tumor antigens (proteins, peptides, DNA or RNA) and administered by subcutaneous injection.

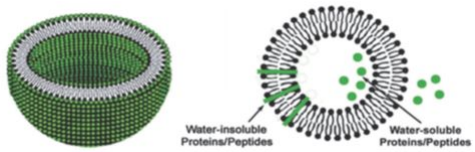


Figure 1: Versamune nanoparticles

The initial concept for Versamune® was first discovered and developed in 2005 by Professor Leaf Huang, at the University of Pittsburgh, School of Medicine. The Versamune® technology is based on the use of immune activating cationic (positively charged) lipids that spontaneously form spherical nanoparticles in aqueous media. Huang, a world-renowned expert in liposome drug delivery and non-viral gene therapy, was familiar with the ability of cationic lipids to effectively deliver DNA into the cytoplasm of cells. PDS's targeted research and development efforts identified critical structural characteristics of bio-active lipids, and then refined and built upon that initial concept.

The resulting Versamune® technology is believed to induce active and potent disease-specific helper and killer T-cells, while simultaneously suppressing the tumor's defenses, are due to the following:

1. The specific design and composition of the Versamune® nanoparticles, which are sized to mimic viruses, promotes uptake of nanoparticles by the dendritic cells of the immune system. Versamune ® the promotes internalization into the cell endosomes and destabilization of endosomal membranes. The associated disease-specific antigens are then processed and released, into the cytoplasm. As a result the antigens are able to access both the MHC Class I and MCH Class II presentation pathways to prime CD8+ killer T-cells and CD4+ helper T-cells respectively.

   Delivery into the right compartments of the cell leads to effective processing of the antigen and cross presentation of the processed antigen to CD8+ T-cells, therefore overcoming a key limitation of vaccine technologies.

2. The structure of the cationic lipids induces specific activation of the Type I interferon (IFN-1) signaling pathway and the related down-stream cytokines and chemokines. IFN-1 activation is known to be highly important in the activation and proliferation of CD8+ T-cells.

   a. Localized induction of IFN-I at the injection site and within the lymph nodes restricts the cytokine and chemokine induction as well as resulting inflammation to the lymph nodes. Minimal systemic/blood stream inflammation limits toxicity, and the lymph node-localized cytokine induction promotes T-cell potency.

   b. Specific/targeted activation specifically of the IFN-I pathway eliminates the non-specific immune activation induced by the current approaches and leads to induction of the correct/required phenotype of active polyfunctional T-cells that present effective tumor targeting and killing.

PDS0101

We believe PDS0101, our lead product candidate, can, if ultimately approved, fundamentally improve patient outcomes and transform the management of HPV-related cancers. PDS0101 combines the utility of PDS' Versamune®, versatile multi-functional platform technology, with a proprietary mix of HPV 16 antigens, the most virulent high-risk type and by far the most prevalent in patients with advanced HPV- associated cancer.

Approximately 43,000 patients are diagnosed with HPV- associated cancers in the US each year, a number unlikely to be impacted by increased use of HPV preventative vaccines in the next decade. HPV associated cancers include oropharyngeal (head and neck) cervical, vulvar, anal and penile cancers. Cervical cancer is the most common HPV-associated cancer in women and there are about ~12,000 new cases diagnosed annually. The incidence of cervical cancer remains steady.

Head and neck cancers have been reported to be increasing in recent years and have been described as a silent epidemic attributed to HPV infection. A recent study showed the overall prevalence of oral HPV infection to be 11.5% in men and 3.2% in women, or 11 million men and 3.2 million women in the United States. High-risk oral HPV-16 was over three times more common in men. Over 70% of oropharyngeal cancers are estimated to be HPV-associated in developed Western countries. It has been reported that about 90% of the oral squamous cell carcinoma (OSCC) tumors were positive for HPV-16. The US National Cancer Institute (NCI) estimated that in 2013 about 36,000 people in the US would be diagnosed with OSCC. For 2017 the projections were increased to 49,670 new cases with an estimated 9,700 deaths. The current treatment options are surgery, radiation, chemotherapy or a targeted therapy, including checkpoint inhibitors.

PDS0101 Phase 1 Clinical Data

PDS completed a Phase 1 trial of PDS0101, which was conducted at three sites in the United States. The study was an Open-label Escalating Dose Study to Evaluate the Safety, Tolerability, and Pharmacodynamics of PDS0101 in subjects with Cervical Intraepithelial Neoplasia (CIN) and high-risk Human Papillomavirus (HPV) infections. The study included 3 cohorts of 3 to 6 subjects each, based on a modified “3 + 3” dose-escalation study design.

The study enrolled Cohort 1 and progressed through Cohort 3, with each subsequent cohort receiving a higher dose of PDS0101. Successive cohorts all received a constant dose of the HPV-16 E6 and E7 antigens. Subjects were given three subcutaneous injections of PDS0101, three weeks apart, and blood was drawn 14 days after each injection, as well as 90 days after the last injection. HPV-specific CD8+ T-cells were quantified using both the Interferon- ELISPOT assay (quantifies all HPV-specific T-cells) granzyme-b ELISPOT assay (specifically quantifies active HPV-specific CD8+ T-cells). Dosing and dose escalation were based on safety evaluation for determination of potential dose-limiting toxicity (DLT).

A total of 12 subjects were enrolled. We believe the data show a strong induction of active HPV-specific killer T-cells (CD8+) observed with quantifiable amounts of the CD8+ T-cells retrieved from patient blood 14 days after treatment.

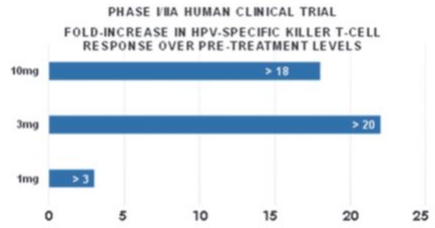


Figure 2: CD8+ T-cell data generated by Granzyme-b ELISPOT in the phase 1 clinical trial

The CD8+ T-cells results seen in the Phase 1 study confirmed preclinical projections of high levels of active granzyme-b inducing, HPV-specific CD8+ T-cells. The results obtained 90 days after the last injection also confirmed preclinical projections of memory T-cell induction. Of note, T-cell responses were independent of patient genetic/HLA sub types.

No dose-limiting toxicities were observed, even at the highest tested dose of 10mg. A dose of approximately 3mg has been selected to move forward into the upcoming PDS0101 Phase 2 clinical studies.

During the third quarter of 2019, PDS received Institutional Review Board, or IRB approval to perform a retrospective analysis of the clinical benefit achieved by the patients who participate in the phase 1 clinical trial. Despite most of the patients being infected with multiple HPV strains other than HPV16, rapid and complete regression of pre-cancerous lesions was documented in at least 6 out of 10 patients within 1-3 months of treatment, strongly suggesting that the T-cells induced by PDS0101 were clinically active. This information strongly suggests the unique ability of PDS0101 to generate potent and biologically active CD8+ T-cells in-vivo. Two patients who had regression by cytology were not considered clinical responders despite the seemingly positive outcome. One patient regressed to atypical cells of undetermined significance at the first post- treatment evaluation at 3 months, but residual HPV was still detected. Another patient had complete regression by cytology at every post-treatment evaluation but had residual CIN by colposcopy. All responders remained disease-free though the 2-year evaluation period, suggesting a durable immune response.

PDS focused its clinical strategy on areas of more severe unmet medical need in which PDS0101 will be combined with other treatment modalities such as checkpoint inhibitors, immune-cytokines and chemoradiation to provide improved clinical benefit to patients. PDS feels that due to the ability of PDS0101 to generate potent HPV specific killer T-cell response in-vivo, that the quickest path to demonstrating proof of concept in a larger trial with the least risk would be to perform these studies in combination with synergistic agents in indications where a more effective therapy is needed. The three planned trial described below are designed to focus on efficiency and risk mitigation to proof of concept.

PDS0101 + Keytruda® in HPV-positive recurrent or metastatic head and neck cancer

We have a collaboration agreement with a subsidiary of Merck & Co. (known as MSD International GmbH outside the United States and Canada) to combine PDS0101 with Merck's anti-PD-1 checkpoint inhibitor, Keytruda®, in a Phase 2 human clinical trial for treatment of HPV-positive recurrent or metastatic head and neck cancer. On October 28, 2019, we entered into an amendment to the existing clinical trial collaboration agreement to evaluate the combination of PDS's lead Versamune®-based immunotherapy, PDS0101, with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase II clinical trial. The planned clinical trial will now evaluate the efficacy and safety of the combination as a first-line treatment (rather than second or third line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection. The modification to the clinical trial design to evaluate PDS0101 in combination with KEYTRUDA® as first-line treatment comes as a result of Merck's approval by the FDA on June 10, 2019 for first line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) using KEYTRUDA® in combination with platinum and fluorouracil (FU) for all patients and as a single agent for patients whose tumors express PD-L1 as determined by an FDA-approved test.

The trial will be sponsored and funded by PDS and is expected to begin in the first half of 2020. The trial is designed to dose 96 patients with standard of care 200 mg IV KEYTRUDA® in 21-day cycles in combination with subcutaneous injection of PDS0101 for the first 4 cycles. PDS0101 will be administered again on the 12th treatment cycle in combination with KEYTRUDA®. A safety analysis is planned of the first 12 patients after cycle one and this information is expected in the fourth quarter of 2020. An interim analysis is planned in the second half of 2021. This study has the potential to validate the efficacy and safety of PDS0101 in combination with a checkpoint inhibitor and this study could lead the way for novel combination therapies in immuno-oncology.

PDS0101 + Checkpoint Inhibitors M7824 and NHS-IL12

We previously announced that we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) for the development of the PDS0101 HPV cancer immunotherapy in combination with other immune-modulating agents as a potential treatment for all types of advanced HPV-related cancers. Under the agreement, we will collaborate with the NCI's Genitourinary Malignancies Branch (GMB) and Laboratory of Tumor Immunology and Biology (LTIB) with plans to conduct a Phase 2 clinical study evaluating PDS0101 with two promising novel immune-modulating agents M7824 and NHS-IL12 being studied at NCI as part of a CRADA with EMD Serono (Merck KGaA). This study is anticipated to start in the first half of 2020. The CRADA also involves preclinical evaluation of PDS0101 in combination with other therapeutic modalities upon the mutual agreement of both parties.

All three agents have demonstrated efficacy as monotherapies in early studies. The phase 2 clinical study has been approved by the IRB and published is expected to enroll 30 subjects. M7824 is a novel first-in-class bifunctional fusion protein, a TGF-β "trap" fused with a human antibody against PD-L 1. NHS-IL12 is a novel immunocytokine conjugate consisting of two IL12 heterodimers fused to the NHS76 antibody. Both agents have been shown to be well tolerated in on-going clinical trials. This trial will evaluate the objective response rate of this novel combination in patients with advanced HPV associated cancers.

PDS0101 + Chemoradiotherapy (CRT)

PDS Biotech anticipates a Phase 2 clinical study with a major cancer research center to begin in the first half of 2020. If initiated, the clinical study would likely investigate the safety and anti-tumor efficacy of the PDS0101-CRT combination, and their correlation with critical immunological biomarkers in patients with locally advanced cervical cancer. T-cell inducing power of Versamune® has the strong potential to enhance efficacy of the current standard of care chemo-radiotherapy. PDS Biotech is currently in negotiations regarding a definitive agreement concerning the investigator initiated Phase 2 study and the scope and nature of such study will be subject to the terms of the definitive agreement, once agreed to by the parties.

Other Development Programs

PDS0102 (TARP-expressing cancers) for the treatment of prostate and breast cancers

Prostate cancer: Based on a promising clinical study run by the NCI using TARP antigens, PDS and the NCI are collaborating to develop a Versamune® platform-based immunotherapy for prostate cancer. PDS0102 has been successfully formulated. A decision will be made as to when PDS0102 clinical studies will be initiated.

Prostate cancer is the most common non-skin cancer in the United States. Over 30,000 men die from the cancer every year according to the Prostate Cancer Foundation, and over two million Americans currently have prostate cancer. A recent report projects that the prostate cancer market will grow at a compound annual growth rate of 9.5%, from $7.6 billion in 2014 to $13.6 billion by 2021.

PDS0103 (MUC-1 expressing cancers) for the treatment of colorectal, breast, ovarian and lung cancers

PDS0103 is based on novel agonist antigens of the mucin-1 (MUC-1) oncogenic C-terminal region developed by the laboratory of Dr. Jeff Schlom, head of Tumor Biology at the NCI. MUC1 is highly expressed in multiple tumor types and has been shown to be associated with drug resistance and poor prognosis for a range of human tumors. The novel agonist peptides, compared to the native peptides, more efficiently enhance production of IFN-γ by peptide activated human T cells, and also more efficiently lyse human tumor cell targets in an MHC-restricted manner. It is also known that high avidity T-cells can lyse targets with 1,000-fold lower peptide-MHC complexes. The enhancer agonist epitopes developed induce higher avidity T-cells than the native antigens and has been demonstrated to be a successful strategy to enhance number and avidity of T-cells for MUC-1 directed immunotherapy.

These MUC-1 antigens have been licensed from the NCI for use with Versamune ® in ovarian, breast, colorectal and lung cancers.

We believe that an effective and safe immunotherapy targeting solid tumors expressing MUC-1 will gain rapid acceptance as a monotherapy in early-stage disease and initially as a combination therapy in later stage disease.

Colorectal cancer (CRC): Colorectal or colon cancer, includes cancerous growths in the colon, rectum and appendix. It is the third most common form of cancer and the second leading cause of cancer-related death in the Western world. Global Markets estimates the colorectal cancer market to grow at 3% annually from $8.15 billion in 2015 to $11 billion in 2025 in the eight major markets, US, UK, England, France, Italy, Japan, China and Germany. We believe that there is significant market opportunity for immunotherapy, especially in early stage CRC disease where there is a lack of novel treatments outside chemotherapy.

Breast cancer: Breast cancer is a leading cause of cancer-related mortality among women worldwide. IMS Health reports that sales of breast cancer treatments will increase by an average of 5.8% a year in nine major markets, increasing from a value of $9.8 billion in 2013 to $18.2 billion by 2023.

Ovarian cancer: Ovarian cancer is the most common cause of death from gynecological tumors. Nearly 60,000 cases of ovarian cancer are diagnosed in the following seven major markets (the United States, Japan, Germany, France, Italy, the United Kingdom and Spain) each year. The five-year survival rate of ovarian cancer patients remains below 20%. The American Cancer Society reports that in the US about 22,240 women will receive a new diagnosis of ovarian cancer, and about 14,000 women will die from ovarian cancer in 2018. We believe that there is a significant market opportunity for immunotherapy especially in early stage disease where there is a lack of novel treatments outside chemotherapy.

Non-Small Cell Lung Cancer (NSCLC): NSCLC is the leading cause of cancer-related mortality in the major pharmaceutical markets. There is still a clear unmet need in the treatment of NSCLC despite products such as Alimta®, Avastin®, Iressa® and Tarceva®. The NSCLC treatment market is expected to reach $12.2 billion by 2025. Growth is expected to be driven by novel therapies entering the squamous cell carcinoma market segment, which is currently lacking effective treatment, unlike the non-squamous market segment.

PDS 0104 (TRP2 expressing cancers) for the treatment of melanoma

PDS has performed substantial preclinical work in advanced melanoma tumor models where we have observed the ability of PDS0104 to overcome immune suppression and inhibit growth of B16 melanoma tumors (*Vasievich et al, Molecular Pharmaceutics, 2012, 9, 2, 261-268*). Preclinical studies have also demonstrated a strong synergy between PDS0104 and checkpoint inhibitors, resulting in dramatically improved antitumor response and prolonged survival.

Melanoma is a malignant tumor of the melanocytes. Melanoma is primarily a skin tumor, although it may also occur less frequently in the melanocytes of the eye. It is currently the seventh most common cancer in the US. Melanoma comprises 5% of all skin cancers. The most common causes are exposure to ultra violet radiation from the sun, leading to damage to the DNA of the melanocytes of the skin, family history, an impaired immune system and atypical moles on the body. The American Cancer Society estimated that there will be about 91,270 new cases of melanoma in 2018, and over 9,000 deaths. No effective therapies existed for advanced cancer until the immunotherapy Yervoy® was approved by the FDA in March of 2011.

A Summary of the Current State-of-the-art

Two approaches, dendritic cell vaccines and CAR T-cell immunotherapies, are the two commercial/FDA approved technologies that have presented the best promise to date in addressing other technologies' inability to effectively present antigens to the dendritic cells inside the body:

Dendritic Cell Vaccines: Dendritic cell vaccines eliminate the need to target and deliver antigens to dendritic cells *in-vivo*. In these products, immature dendritic cells or monocyte precursors of the patient's dendritic cells are removed from the patient's blood and cultured outside the body. The dendritic cells are then treated with tumor antigens, and matured dendritic cells are re-infused into the patient to present the processed antigen material to the patient's T-cells.

Recent data reported with Provenge®, a prostate cancer vaccine, suggests that its induced immune responses are long-lived, with strong T-cell responses still observed in most surviving patients at two years after treatment. Nevertheless, this approach does not appear to address the immuno-suppressive environment in tumors, or provide immune activation/stimulation necessary to enhance activity of primed T-cells. Importantly, recent studies have demonstrated that antigen uptake and processing is still suboptimal when dendritic cells are treated ex-vivo.

CAR T-Cell Immunotherapy: CAR T-cell immunotherapy is based on manipulating T-cells collected from patients' own blood. After collection, T-cells are genetically engineered to produce special receptors on their surface called chimeric antigen receptors ("CARs"). CARs are proteins that allow T-cells to recognize a specific protein (antigen) on tumor cells. These engineered CAR T-cells are then grown in the laboratory until they number in the billions. This expanded population of CAR T-cells is then intravenously infused into the patient. After the infusion, the T-cells are expected to multiply in the patient's body and, with guidance from their engineered receptor, recognize and kill cancer cells that display the antigen on their surfaces. Two CAR-T therapies have been approved to treat large B-cell lymphoma, Kymriah® and Yescarta®, and others are being tested in clinical studies.

CAR T-cell immunotherapy overcomes the need to perform *in-vivo* antigen processing and uptake by dendritic cells. Recent data in blood cancers have shown promising results with a high rate of complete remissions. These results confirm the ability or importance of killer T-cells in targeting and killing cancerous cells. Nevertheless, this approach does not appear to address the immuno-suppressive environment in solid tumors, and can cause significant side effects. Perhaps the most troublesome side effect is cytokine-release syndrome. The infused T-cells release cytokines, leading to a rapid and large presence in the bloodstream. This can cause dangerously high fevers and precipitous drops in blood pressure. Relatively high cost and complex manufacturing processes for CAR-T therapies may also limit the broader applicability of CAR T-cell immunotherapies in the long run. High numbers of infused T-cells can result in extremely high and debilitating systemic inflammation. In some recent clinical studies, patient deaths were reported as a result of high numbers of infused T-cells. These clinical studies were then suspended by the FDA.

Other promising approaches under evaluation in clinical studies are:

Live Vectors: This approach uses live vectors, predominantly live viruses or live bacteria, with added copies of a plasmid that encodes the protein antigen DNA sequence. The protein is then secreted by the virus or bacteria once the DNA is successfully transfected into the dendritic cells. Studies have shown this approach can result in successful stimulation of T-cells and antibodies. Systemic toxicities have been reported with some live virus and bacteria technologies administered by intravenous infusion. Certain clinical studies have been suspended due to patient deaths suspected, but not confirmed, to have resulted from treatment-related toxicities.

Antibodies: This approach uses dendritic cell targeting antibodies linked to tumor antigens in order to facilitate dendritic cell uptake of those antigens.

Electroporation: This approach involves generation of electrical pulses through the skin. This technology delivers antigenic DNA into the dendritic cells residing beneath the skin. The protein then has to be secreted by the dendritic cells once the DNA has been successfully delivered and transfected into the dendritic cells. Studies have shown this approach can result in successful stimulation of T-cells and antibodies. Several of the technologies summarized above have not demonstrated the ability to effectively activate the necessary immunological mechanisms required to induce optimal killer T-cell responses. Additionally, many of these approaches do not activate mechanisms to combat or reduce immuno-suppressive cell populations within tumors. These drawbacks may lead to suboptimal responses, and the need to combine them with other technologies in the long run to improve their clinical responses.

Some efforts to address the immuno-suppressive environment have focused on developing antibodies focused on blocking immune checkpoints. These are known as the checkpoint inhibitors. Checkpoint inhibitors have had the most developmental attention and commercial success to date in the field of cancer immunotherapy. The function of checkpoint inhibitors is to block normal proteins on cancer cells, or the proteins on T-cells that respond to them. The result is to make cancer cells more visible to T-cells. This then helps generate a T-cell assault on the cancer. The use of checkpoint inhibitor antibodies to overcome tumor immune suppression is known to present the potential for triggering autoimmune disease. To date, more than six checkpoint inhibitors have received rapid approval from the U.S. Food and Drug Administration, or FDA. These include ipilimumab (Yervoy®), pembrolizumab (Keytruda®), and nivolumab (Opdivo®).

Adjuvant-Based Cancer Vaccines: Adjuvant-based cancer vaccines appear to be quite well tolerated, with the most commonly reported adverse events being injection site reactions and systemic toxicities. These systemic inflammatory immune responses are sometimes caused by the use of the immune activators, known as adjuvants. Such adjuvants may have the potential to induce high cytokine levels in the blood, which can sometimes lead to severe side effects as a result of cytokine storms.

Combination Immunotherapy

One common clinical goal of administration of immunotherapies to cancer patients is to spark a self-sustaining attack against cancer cells by the T cells, thereby producing long-term clinical benefit. Currently, there are approximately 2,000 immunotherapeutic agents in development. Some cancer patients respond better to the immunotherapies than others, due in part to the factors described above.

The limitations of current immunotherapy technologies as cancer monotherapies are now resulting in increasing testing of multiple cancer drugs in combination. As a result, combination immunotherapy is now generally believed to be the latest frontier in cancer research, and over a thousand such combination therapy clinical studies are currently ongoing. Due to the ability of the checkpoint inhibitors to alter the tumor's immune suppressive environment by blocking the immune checkpoints, the vast majority of the combination studies involve checkpoint inhibitors. However, due to the known need for CD8+ T-cell induction, checkpoint inhibitors have only generally been proven to be optimally clinically successful in a minority of treated patients to date.

Thus far, nivolumab with ipilimumab, which targets PD-1 and CTLA-4 respectively, is the only checkpoint-inhibitor combination approved for clinical use. It was approved to treat metastatic melanoma by the FDA in 2015. In a published study report, this combination was shown to delay tumor progression in melanoma by a median of 11.5 months, almost twice as long as in those on nivolumab alone, and almost four times as long as in people treated with only ipilimumab (Larkin, J.). Then, in October 2017, in a published study report, researchers demonstrated that this combination extended survival times: people with melanoma lived longer on the combined treatments, with 58% still alive after three years compared with 52% of those treated with nivolumab alone.

However, these improved survival rates were paired with reports of increased toxicity. Almost 60% of people taking the combination experienced severe side effects such as colitis or diarrhea - three times as many as those treated with nivolumab, and twice as many as those treated with ipilimumab.

PDS believes that rational design of combination immunotherapies using agents that promote synergy with each other and reduced potential for compounded toxicity would substantially improve potential for combination therapies to deliver improved clinical benefit for cancer patients. PDS believes that the fact that Versamune® appears to activate the appropriate combination of immunological pathways that promote strong CD8+ T-cell induction, while also altering the tumor's microenvironment to make the tumor more susceptible to T-cell attack, makes it an ideal complement to the checkpoint inhibitors to enhance their potency. In addition, the differences in mechanism of action between Versamune® and checkpoint inhibitors, as well as the initial demonstrated safety profile of Versamune®, suggests that these combinations may be much better tolerated by patients than many or most other combination therapies involving checkpoint inhibitors.

Example 1: Studies to understand the effect of Versamune ®-based immunotherapy combined with a checkpoint inhibitor in a difficult-to treat preclinical tumor model:

To determine if checkpoint inhibitors enhanced the anti-tumor response of Versamune ®, preclinical studies were performed employing the B16F10 melanoma model. B16F10 is a notoriously difficult tumor to successfully treat with antigen-specific immunotherapy, and monotherapy. One reason is that many of the antigens targeted are self-antigens to which there is some degree of immune tolerance. A previous study performed by PDS demonstrated that TRP2 antigen dose was important in the ability of R-DOTAP to break the tumor's immune tolerance, and a 75µmol dose was demonstrated to inhibit tumor growth but did not induce regression.

The Versamune® plus Trp2 formulation was shown to induce a strong CD8 T cell response. Trp2 is a 9aa tyrosinase related peptide presented by the H-2K b molecule ($Trp2_{180-188}$: SVYDFFVWL). Subcutaneous injection with Versamune® and Trp2 resulted in strong CD8+ T-cell ELISPOT responses whereas Trp2 alone did not elicit any T-cell response (Figure 3). To determine whether anti-PD1 treatment synergized with Versamune® and Trp2 treatment in slowing the growth of B16 melanoma, mice were implanted with B16F10 melanoma and injected with Versamune® and Trp2 when tumors reached a size of 3mm. In addition, some groups received 5 injections of anti-PD1 antibody.

Treatment with Versamune® plus Trp2 (PDS0104 prototype) resulted in significant slowing of tumor growth compared to naïve or anti-PD1 only groups, which demonstrated no impact on tumor growth.

When Versamune® plus Trp2 vaccination was combined with anti-PD1 treatment a synergistic effect was apparent resulting in a more dramatic inhibition of tumor growth and an extension of survival (Figure 16 B-C). Tumor growth rate was observed to increase upon halting the anti-PD1 treatment.

These results strongly suggest an effective immunotherapeutic synergy between the Versamune® T-cell activating platform and the checkpoint inhibitors. Versamune ® may therefore potentially be successfully combined with a checkpoint inhibitor in human combination immunotherapy strategies.

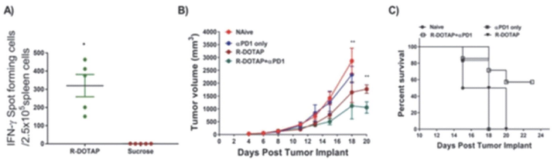


Figure 3: Versamune® (R-DOTAP) synergizes with anti-mouse PD1 checkpoint inhibitor treatment to significantly alter B16 melanoma tumor growth *in vivo.* Groups of C57BL/6J mice (n=5) were treated with the Versamune® plus TRP2 nanoparticles or TRP2 mixed in sucrose buffer on day 0 and boosted on day 7. A) Antigen specific CD8+ T cell responses in spleen were assessed 7 days after the second vaccination by ELISPOT assay. B-C) Mice were implanted subcutaneously with 1 X 10^5 B16.F10 tumor cells and were subcutaneously injected with two doses of Versamune® plus TRP2 nanoparticles on day 5 and 12 after tumor implant. For anti-mouse PD1 therapy, each mouse received five doses of 200 µg of anti-mouse PD1 antibody delivered i.p. at 3-day intervals starting on day 5 after tumor implant. B) Mean tumor volume ± SEM (n=5) in vaccinated or naïve mice. C) Survival over the course of the study.

Versamune® Mechanisms of Action (MOA)

We believe that the Versamune® platform has a multi-functional mechanism of action, or MOA, which is responsible for its strong antigen-specific T-cell activity, that could potentially lead to clinical confirmation of efficacy (*Ghandapudhi et al, J. Immunology, June 15, 2019, 202 (12) 3524-3536*). PDS continues to further study and validate some of these detailed molecular signaling mechanisms.

The section below summarizes studies that have been performed to confirm the mechanisms by which the Versamune ®-based products elicit strong anti-tumor responses apparently without the toxicities typical of current immunotherapy.

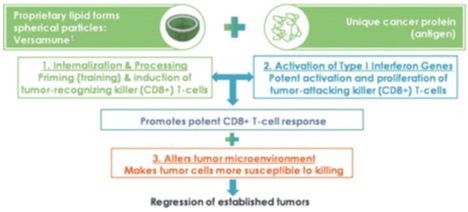


Figure 4: Summary of the versatile and multi-functional mechanism of the Versamune® platform that leads to demonstrated anti-tumor activity

Antigen Uptake

The critical first step in the process of effectively priming T-cells is uptake of disease-related antigens in the formulation. Versamune ® exploits the well-studied function of dendritic cells to “take up” particulate matter, and no targeting mechanisms are therefore believed to be required to facilitate this uptake. The positive charge of Versamune® leads to enhanced association with negatively charged cell surfaces, resulting in high internalization by the dendritic cells.

To confirm this effective uptake by dendritic cells, a number of in-vivo confirmatory studies were successfully completed:

- A bio-distribution study in mice demonstrated that, four hours after subcutaneous injection of Versamune ®, 80% of dendritic cells in a draining lymph node (where dendritic cells interact with T-cells) had taken up Versamune®. This study also demonstrated that dendritic cells had been effectively activated and matured by Versamune®.

- Pharmacokinetic and absorption, distribution and excretion studies, in both rats and monkeys, demonstrated an extremely low presence of PDS0101 in the blood circulation (bio-availability 5-6%) after subcutaneous administration. These studies also demonstrated an extremely low presence of PDS0101 in all key organs of the body, with predominant presence in the lymphatic system. These studies confirmed effective uptake of the immunotherapy by the dendritic cells, and a subsequent high presence in the lymphatic system where effective interaction with T-cells can occur.

Example 2: *In-vitro* studies performed to examine the ability of Versamune® to promote antigen uptake and processing by bone marrow-derived dendritic cells (BMDC):

The protein ovalbumin (OVA) was used as a model antigen. Uptake of OVA into BMDC was visualized using Alexa 647-OVA. BMDC were incubated for various times with Versamune ® and Alexa 647-OVA or Alexa 647 OVA alone followed by measurement of Alexa 647-OVA fluorescence by flow cytometry. Although some Alexa 647-OVA uptake was observed in BMDC incubated with Alexa 647-OVA alone, uptake was dramatically enhanced in the presence of Versamune®. Notably, Versamune® facilitated significant uptake within the first 10 minutes and continued throughout the hour (Figure 4).

Presumably, OVA uptake mediated by Versamune ® would deliver OVA into acidic endosomes where OVA processing would be expected to occur. To evaluate processing, PDS utilized DQ-OVA, which is a heavily fluorescent OVA that self- quenches in the intact molecule, but fluoresces when degraded. Incubation of BMDC with DQ-OVA and Versamune ® resulted in a significant shift to red fluorescence indicative of extensive processing and endosomal accumulation. Incubation of BMDC with DQ-OVA and the potent adjuvant LPS did not result in enhanced processing (Figure 5). Thus, in this study, Versamune® promoted rapid protein uptake and processing in BMDC, presumably in the endosomal compartments.

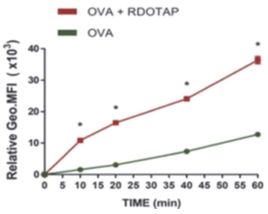


Figure 5: Versamune® enhances protein uptake by dendritic cells

Bone marrow derived dendritic cells were incubated with Alexa-647 conjugated ovalbumin admixed with sucrose or Versamune ® (R-DOTAP) nanoparticles for indicated times and the association of ovalbumin with BMDCs was represented as mean fluorescence intensity.

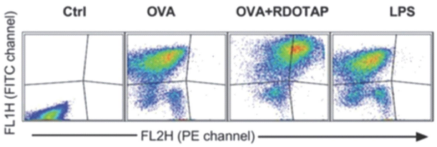


Figure 6: Versamune® enhances processing of antigen by dendritic cells

Bone marrow derived dendritic cells were incubated with DQ conjugated ovalbumin admixed with sucrose or Versamune ® nanoparticles or LPS (1µg/ml) for indicated times and the association of ovalbumin with BMDCs was represented as mean fluorescence intensity.

DQ-Ovalbumin processing at 60 minutes was measured by assessing the fluorescence in the FITC channel (FL1H) and the fluorescence in the PE-channel (FL2H) which represents the ovalbumin processing.

To further examine the ability of Versamune® to influence cross presentation of antigens to killer T-cells (CD8+) by dendritic cells, studies were performed utilizing the B3Z T cell hybridoma, which expresses a T-cell receptor specific for the CD8-specific SL9 peptide of ovalbumin presented by H-2Kb. B3Z cells express a reporter lacZ gene under the control of the nuclear factor of activated T cells (NFAT) promoter providing a rapid and sensitive assay for the processing and presentation of SL9 antigen by dendritic cells. BMDCs were incubated with a long ovalbumin peptide ($OVA_{241-270}$) containing the SL9 epitope formulated with Versamune® nanoparticles or sucrose buffer for 1hr at 37 oC to load the peptide on to BMDCs. Excess peptide was removed by washing and BMDCs were then co-cultured with B3Z cells overnight. The efficiency of SL9 peptide cross presentation by BMDCs was measured using a colorimetric lacZ detection assay. While incubation of BMDC with peptide alone resulted in some cross presentation to B3Z cells, the addition of Versamune® nanoparticles resulted in maximal stimulation with approximately 100-fold less peptide (Figure 6). These results suggested that Versamune® dramatically enhances cross presentation of antigens to CD8+ T-cells.

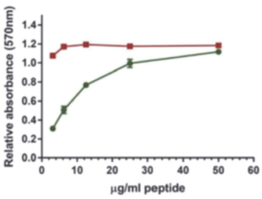


Figure 7: Versamune® promotes antigen cross-presentation to killer T-cells (CD8+) *in-vitro*

BMDCs were pulsed for 10 minutes with indicated concentrations of OVA (241-270) peptide admixed with sucrose (green) or Versamune ® (red) and co-cultured with B3Z cells overnight and lacZ production by OVA peptide-stimulated B3Z was measured using lacZ colorimetric assay.

Overall the studies summarized in Example 1 demonstrate the ability of Versamune ® to potentially overcome a significant limitation of current immunotherapeutic approaches. This critical limitation is the sub-optimal uptake, processing and cross-presentation of antigens resulting in weak induction of tumor-targeting killer T-cells.

Antigen Presentation

One of the most important characteristics of the Versamune ®-based lipids is their ability to facilitate entry of antigens into the cytoplasm of dendritic cells, and subsequent efficient presentation to T-cells leading to effective T-cell priming. This characteristic is expected to help the Versamune®-based products overcome one of the most significant obstacles facing the field of cancer immunotherapy.

The use of cationic lipids in cancer and infectious disease immunotherapy has gained significant attention due to the work of Prof. Leaf Huang and the unique properties of these lipid particles in delivering their content effectively into antigen presenting cells such as dendritic cells.

To confirm that Versamune® facilitates antigen presentation to CD8+ (killer) and CD4+ (helper) T-cells via MHC Class I and Class II, respectively, a number of in-vivo and in-vitro confirmatory studies were performed.

Example 2: In-vivo studies to confirm the ability of Versamune ® to perform cross presentation to CD8+ T-cells

To directly examine cross presentation *in vivo* following Versamune® administration with antigen, these studies utilized an adoptive transfer model in which OT-I T-cell receptor (TCR) transgenic T cells specific for the CD8 epitope SL9 of ovalbumin (OVA) used as a model antigen and presented by H-2Kb were labeled with carboxy fluorescein succinimidyl ester (*CFSE*), a fluorescent cell staining dye and transferred into normal C57BL/6 mice.

Activation and proliferation of OT-1 cells in the adoptive transfer mice requires *in-vivo* processing of whole OVA into the SL9 epitope and presentation on the H-2Kb MHC class I molecule, i.e. cross presentation. Mice were then injected in the footpad with 1µg of whole OVA admixed with either sucrose or Versamune®. Proliferation of the transgenic T cells in the draining popliteal lymph node was assessed by flow cytometry measuring CFSE dilution in the transgenic T cells.

The draining lymph nodes (DLN) draining the Versamune ® + OVA footpads were noticeably enlarged, and this was reflected in an increased total cell number isolated per lymph node. There was also a significant increase in total OT-1, both divided and undivided in the Versamune® + OVA-treated mice compared to OVA alone (Figure 7).

Thus, Versamune® facilitated processing and MHC class I cross presentation of whole protein to CD8+ T cells in the draining lymph node when administered subcutaneously. Similar results were obtained utilizing class-II OVA-specific transgenic T-cells demonstrating that Versamune® facilitated MHC class II presentation of whole protein to CD4+ T cells in the draining lymph node when administered subcutaneously.

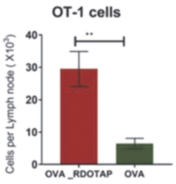


Figure 7: Versamune® (R-DOTAP) promotes antigen cross presentation *in-vivo* leading to superior proliferation of OT-1 CD8+ T-cells

Total number of antigen specific cells in the draining popliteal lymph nodes in each vaccinated mouse were enumerated using hemocytometer and antigen specific CD8 T cell expansion was measured by CFSE dilution assay and total number of OT-1 CD8T cells.

Immune Activation

The ability of certain structurally-specific cationic lipids to act as potent immune activators was first reported by Prof. Leaf Huang. Subsequent studies have identified the fact that the cationic lipids activate (or upregulate) the type I interferon genes. The type I interferon signaling pathway is well documented to be highly important in activation and proliferation of killer T-cells. PDS's studies have demonstrated that cationic lipids utilize certain pathways to upregulate type I interferons.

To better understand how the cationic lipids induce potent immune activation without the typically observed inflammatory toxic side effects, a number of further studies were performed.

Example 3: Studies to understand the immunological effects of Versamune ® and resulting T-cell responses

To examine the immunostimulatory effect of Versamune ® in the draining lymph node, mice were injected with Versamune ® nanoparticles in the footpad and inflammatory gene expression was monitored in purified CD11c dendritic cells from the draining or non-draining popliteal lymph nodes after 4h or 24h by Nanostring multiplex analysis.

Among the inflammatory genes examined, the strongest genes up-regulated were those involved in the type I interferon pathway. These included IFNα, IFNβ, CXCL10, and Stat 1. No induction of classical NFκB dependent cytokines was observed (Figure 8). This result suggested that Versamune® is capable of inducing type I IFN in dendritic cells.

To directly examine type I IFN production by dendritic cells, BMDC were incubated with Versamune ® or LPS as a positive control for 18h and type I IFN was measured in the B16-Blue bioassay. There was a significant dose dependent induction of type I IFN in BMDC by Versamune®.

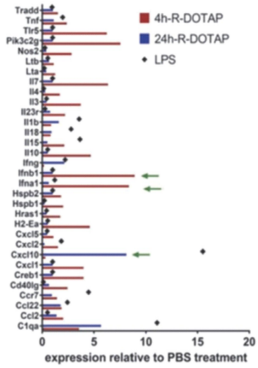


Figure 8: Versamune® (R-DOTAP) administration induces in-vivo lymph node production of Type I interferons known to be critical for CD8+ T-cell activation.

Mice were injected with Versamune® or sucrose in the foot pad and draining popliteal lymph nodes were harvested from each mouse and CD11c cells from pooled lymph nodes were sort purified. Relative gene expression from sort purified CD11c cells from Versamune® or LPS injected mice were analyzed using Nano string technology.

Cytokine/Chemokine Induction:

In preclinical studies, cytokine and chemokine induction were observed within lymph nodes within 24 hours of a single subcutaneous injection, and persisted for at least 5 days. This is important as cytokines and chemokines are known to be important in the activation and proliferation of T-cells (Figure 9). A separate study performed to evaluate the effect of Versamune® on induction of 20 key cytokines and chemokines demonstrated that, unlike a traditional T-cell activating immunotherapy used as a positive control, that Versamune® injection led to negligible increase in blood cytokine levels above normal baseline levels. This finding was important for 2 reasons:

1. Localized cytokine induction within the lymph nodes at the site of required T-cell activation could enhance activation of primed T-cells.

2. Localized induction of cytokines within the lymph node with negligible presence in the blood circulation minimizes potential for systemic toxicities, and improves clinical tolerability of the immunotherapy.

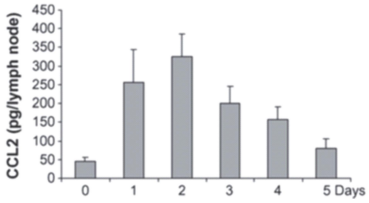


Figure 9: Single subcutaneous injection of PDS0101 leads to sustained and elevated levels of the important CD8+ T-cell activating chemokine CCL2 (MCP-1).

On day 0, mice (n=3) were injected with PDS0101formulation.

On the indicated days, the mice were sacrificed and the draining lymph nodes collected.

The draining lymph nodes were homogenized in 100 µl ELISA buffer (10% FBS in PBS) and then analyzed by ELISA assay.

Activation and Proliferation of T-Cells:

As noted above, Versamune® was demonstrated to induce production of various chemokines in lymph nodes. Chemokines play a major role in selectively recruiting monocytes, neutrophils, and T-cells. It was demonstrated that, within a few hours of administering Versamune®, significant T-cell infiltration into the lymph nodes results.

Administration of Versamune® resulted in a visible increase in draining lymph node (DLN) size of wild type mice and this was due to a steady increase in total cell number over a seven-day period (Figure 10). This increase in total cell number was found to be dependent on the ability of Versamune® to induce type I IFN signaling, as this effect was greatly reduced in IFNαR knock-out mice which are devoid of type I interferons.

Type I IFN is known to inhibit lymphocyte egress from lymphoid organs through the up-regulation of CD69, which in turn, inhibits the sphingosine 1 phosphate receptor required for lymphocyte egress. It has now been demonstrated that administration of Versamune® induces type I IFN in the lymph nodes, which in turn, up-regulates CD69 in T cells and natural killer cells resulting in their accumulation in the lymph nodes. This effect facilitates effective interaction of T-cells with dendritic cells leading to effective priming of T-cells.

When Versamune® is administered together with an antigen, strong T-cell priming to recognize the particular antigen, activation and proliferation is facilitated. Figure 11 shows a comparison of T-cell activation between Versamune® and the potent immune activator GM-CSF, demonstrating higher levels of CD8+ T-cell induction by Versamune®.

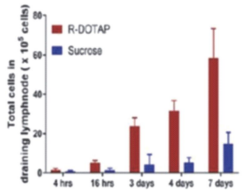


Figure 10:

Versamune® administration induces production of chemoattractant chemokines leading to infusion of T-cells into the draining lymph nodes *in-vivo*.
B6 mice were injected with Versamune® or sucrose and draining lymph nodes were harvested from each mouse, and enzymatically digested lymph nodes were assessed for the total cell number at indicated times. Total infiltrating T cells are shown.

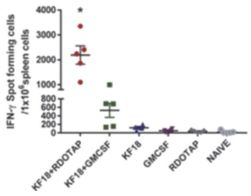


Figure 11:

Versamune® induces high levels of HPV-specific CD8+ T-cells *in-vivo*.

Groups of C57BL/6J mice (n=5) were treated with the indicated formulation containing HPV CD8 T cell epitopes mixed with Versamune, GMCSF, or sucrose on day 0 and boosted on day 7. Antigen specific CD8 T cell responses in spleen were assessed 7 days after the second injection by ELISPOT assay.

Quality of induced T-Cells:

A qualitative factor now known to be highly important in the ability of T-cells to lyse, or kill, infected cells is the quality or potency of T-cells. T-cell quality is directly related to its polyfunctionality, or its ability to induce more than one cytokine. In order to better understand the strength of Versamune®-induced immune responses and their clinical relevance, head-to-head comparisons were made with promising adjuvant-based therapeutic vaccine formulations which had shown promise in preclinical and clinical studies.

We first compared a prototype Versamune®-MUC1 formulation (PDS0103) to two emulsion-based adjuvants in clinical development. Montanide is a proprietary emulsion adjuvant currently being used in peptide-based cancer vaccines. Another potent emulsion-based combination adjuvant formulation specifically designed to induce strong *in-vivo* CD8 T cell responses consists of the 4-adjuvant combination of incomplete Freund's adjuvant, IL-12, GM-CSF, and HBV $_{128-140}$ helper epitope (IFA-Cyt). Mice receiving PDS0103 showed strong responses to both V1A and V2A CD8+ stimulatory. In contrast IFA-Cyt generated an equivalent strong response only to V2A, and Montanide induced responses were significantly lower for both V1A and V2A peptides.

Next, the polyfunctionality (ability to produce multiple cytokines) of induced antigen specific CD8 T cells was assessed by measuring their ability to produce cytokines interferon-gamma (IFN-γ), tumor necrosis factor-alpha (TNF-α) or interleukin-2 (IL-2) by intracellular cytokine staining. In this assay, it was observed that Versamune ®-based formulations stimulated the highest percentages of polyfunctional antigen specific CD8 T cells compared to the other two tested emulsion-based lipid formulations (Figure 13), suggesting that Versamune® may induce not only a higher number of CD8 T-cells *in-vivo*, but also potentially qualitatively superior T cells (higher potency) compared to other typical immunotherapy approaches.

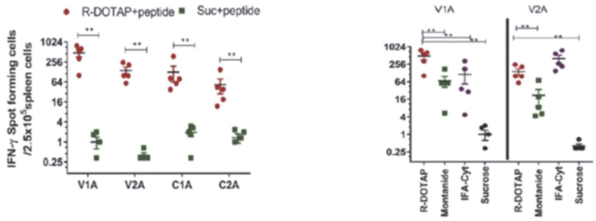


Figure 11: Versamune® (R-DOTAP) formulations containing multiple MUC-1 tumor associated antigens (PDS0103) induce quantitatively superior CD8 T cells responses.

Groups of AAD mice (n=6) were injected with the indicated formulations containing MUC-1 CD8 T cell epitope antigens on day 0 and boosted on day 7. MUC-1 specific CD8 T cell responses in the spleen were assessed 7 days after the second injection by ELISPOT assay. (A) Number of V1A, V2A, C1A, and C2A specific IFN.$_{\gamma}$ producing cells in spleens from mice injected with Human MUC-1 peptides. (C) Number of V1A, and V2A specific IFN.$_{\gamma}$ producing cells in spleen from mice vaccinated with Versamune®, IFN-Cyt or Montanide formulations containing Human MUC-1 peptides. Versamune induces approximately a 10 fold higher number of polyfunctional (the most potent) T-Cells then other leading therapies.

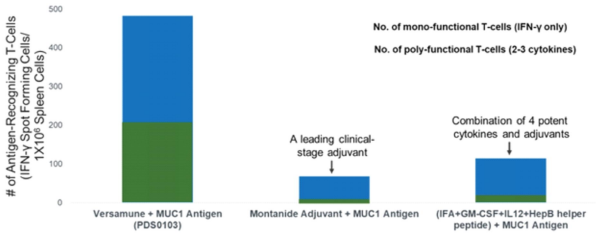


Figure 12: Versamune® (R-DOTAP) formulations containing multiple MUC-1 tumor associated antigens (PDS0103) induce qualitatively superior CD8 T cells responses.

Groups of AAD mice (n=6) were injected with the indicated formulations containing MUC-1 CD8 T cell epitope antigens on day 0 and boosted on day 7. Fraction of V1A or PMA/Ionomycin (positive control) stimulated cells in spleen producing multi-cytokine (IFN.$_{\gamma}$, TNF-α, and IL-2) among the IFN .$_{\gamma}$ producing cells. PMA/Ionomycin is a commonly used *in-vitro* stimulant used to induce cytokine production by T-cells for research purposes.

Enantiomeric Specificity of the Cationic Lipids : Cationic lipids exist as 50:50 racemic mixtures of two asymmetric molecules, each called an enantiomer. Enantiomers are referred to as chiral, meaning they have identical physical and chemical structure and are mirror images of each other. Each of the enantiomers can be regarded as separate chemical entities if they can be demonstrated to possess different biological activity. PDS discovered that the R-enantiomer of the cationic lipid DOTAP is the immuno-active component of the mixture, with the S-enantiomer having weaker immune activating capability. R-DOTAP is the active ingredient now used in Versamune®. PDS's products are the first pharmaceutical products to contain a pure cationic lipid enantiomer, and its use in cancer immunotherapy is protected by several issued patents.

Altering the Tumor Microenvironment to Overcome Immune Suppression

The demonstrated ability of Versamune® to induce effective regression of established tumors strongly suggested that cationic lipids, such as R-DOTAP, could facilitate an altering of the tumor micro-environment sufficient to break tumor immune tolerance and induce killing of tumor cells.

Example 4: Studies to understand the effect of the Versamune®-based immunotherapy on the tumor's microenvironment:

To better understand Versamune®-induced changes within the tumor microenvironment, TC-1 tumor bearing B6 mice were subcutaneously injected on day 0 and day 7 with a Versamune®-based formulation containing a multi-epitope HPV peptide antigen (KF18) and assessed the effector (T-cell) and suppressor T cell (immune suppressive regulatory T-cells) recruitment to the tumor microenvironment on day 26. For comparison, a GMCSF adjuvant-based formulation that has been shown to induce strong CD8+ T cell immune responses *in vivo* in a clinical setting was also evaluated for comparative purposes. ELISPOT analysis (Figure 11) of CD8+ specific T cells (RF9) showed that tumor-bearing mice treated with the Versamune®-based formulation induced a superior sIFN-γ ELISPOT response to the RF9 CD8 T cell epitope detected in the spleens 7 days after the second injection.

Mice treated with GMCSF + KF18 stimulated a modest antigen specific T cell ELISPOT response, while, as expected, no response was observed with KF18 antigen alone, GMCSF, or Versamune® alone. To evaluate the tumor microenvironment during Versamune® induced tumor regression, groups of mice were treated with Versamune® + an HPV multi-peptide mixture containing KF18, with or without GMCSF.

To assess the cell types present within the tumor after various treatments, tumors were removed, enzymatically digested and cell populations analyzed by flow cytometry. CD4 helper T-cells, RF9-specific CD8 killer T-cells, FOXP3+ immune suppressive regulatory T-cells (Treg) were analyzed.

Versamune® + HPV peptide treated mice showed the highest percentage of CD8+ T cells within the tumor, and about 50% of these cells were RF9 specific. GMCSF and antigen, or antigen alone did not induce significant CD8 or CD8-RF9 specific T cell infiltration into the tumors. The CD8/CD4 ratio was highest in the Versamune® + HPV mix group and the Treg/RF9 specific T cell ratio within the tumors was dramatically lower in the Versamune® and HPV mix groups (Figure 14).

These data collectively suggest that Versamune®-based formulations induced a quantitatively superior antigen specific T cell response and the cells were actively recruited to the tumors in large numbers promoting anti-tumor responses and eventually alter the tumor's microenvironment to promote regression and elimination of established tumors.

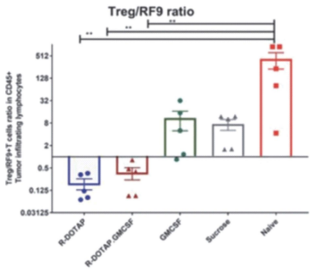


Figure 13: Versamune® efficiently alters effector T-cell to immune suppressor T cell ratio within the tumor, therefore promoting tumor regression.

Groups of C57BL/6J mice (n=5) were injected with the indicated formulation containing a HPV peptide antigen mixed with Versamune ®, Versamune® plus GM-CSF, GMCSF, or sucrose on day 0 and injected again on day 7. Mice (n=10) were implanted subcutaneously with 1 X 10^5 TC-1 tumor cells and were given a single dose of each formulation when the tumors reached an average diameter of 4-5 mm on day 11 and tumor growth was monitored. The mice (n=5) were euthanized 8 days post treatment when the mice showed initial signs of regression and the tumors were processed to assess tumor infiltrating cells. Ratio of CD4/CD8 cells and ratio of immune suppressive Treg cells/RF9 CD8+ positive cells in the enzymatically digested tumor cell suspension were evaluated. Data represent mean ± SEM from each group (n= 5) and experiments are repeated at least 3 times with similar results.

Discussion of the effects of the studied attributes of Versamune® on tumor regression

T-cell-inducing immuno-therapeutic approaches to date have primarily focused on optimizing antigen-specific CD8 T cell induction. These approaches include designs to enhance antigen delivery, uptake and presentation of antigen including approaches such as the use of DNA, viral or intracellular bacterial vectors, nanoparticles, targeting of the antigen to DC through conjugation or pulsing DC in vitro with antigen.

Most of these approaches also include immunostimulatory compounds, typically toll-like-receptor, or TLR, agonists designed to induce the desired cytokine production. Still others include recombinant cytokines like IL-2, IL-12 or GMCSF. PDS's demonstration that the Versamune® platform functions as an activator of the type I interferon pathway in addition to promoting antigen presentation via the MHC Class I pathway, explains the apparent unique ability of Versamune® formulations to induce potent T-cell responses without inclusion in the formulation of extraneous cytokines or TLR agonists.

One of the most effective cancer vaccines reported to date consists of:

1. Anti-tumor antibody;
2. IL-2;
3. Lipid modified peptide;
4. CpG; and
5. Anti-PD1 checkpoint inhibitor.

This complex multi-component immunotherapy induced strong CD8+ T-cell responses and tumor regression in the HPV-positive TC-1 mouse model. However, in the absence of anti-PD1 checkpoint blockade, this product did not induce complete regression of a TC-1 tumor using the same RF9 peptide antigen as in PDS's studies.

In contrast, Versamune® nanoparticles, formulated with HPV peptide antigen KF18, effected complete regression of large TC-1 tumors in mice with a single subcutaneous injection (Figure 15). PDS's studies support the projection that Versamune® nanoparticles, combined with protein or peptide antigens, may possess the critical properties for a powerful CD8+ T-cell immunotherapy. These include:

- Effective antigen delivery to the antigen presenting cells of the immune system
- Antigen uptake and cross presentation to CD4+ and CD8+ T-cells
- Intrinsic and specific immunostimulatory properties through activation of type I interferons; and
- Formation of an antigen depot without the severe injection site reactions observed with emulsions and other approaches.

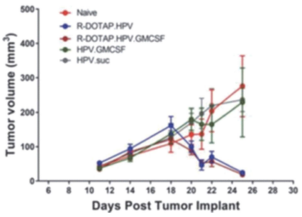


Figure 14: Versamune® (R-DOTAP) efficiently alters effector to suppressor T cell ratio promoting effective regression of HPV-positive TC-1 tumors.

Groups of C57BL/6J mice (n=10) were implanted subcutaneously with 1 X 10^5 TC-1 tumor cells and were given a single dose of a formulation containing HPV CD8 T cell epitopes mixed with Versamune®, Versamune® plus GM-CSF, GMCSF, or sucrose when the tumors reached an average diameter of 4-5 mm on day 11 and tumor growth was monitored. Tumor regression only occurred in the formulations containing Versamune®. Addition of GMCSF to Versamune® appeared to provide no additional benefit.

Anti-Tumor Efficacy in Advanced and Immuno-Suppressive B16F10 Model:

PDS utilized the aggressive subcutaneous B16F10 animal model in order to study Versamune ® anti-tumor efficacy in a well-documented and extremely highly immuno-suppressive tumor microenvironment. This study was a follow-up to above described studies showing potent anti-tumor activity in HPV-positive TC-1 tumors with single doses.

The advanced B16F10 solid tumor model is rarely used in cancer immunotherapy development. More often, the prophylactic model is evaluated, where treatment occurs prior to inoculation with B16F10 tumor cells with the goal of preventing establishment of tumors. This is because once the tumors become well-established, various immune-suppressive mechanisms develop in tumors that are able to suppress T-cell activity. This suppression results in a lack of T-cell anti-tumor effect.

This study utilized an advanced tumor model, with 3 x 10^5 B16F10-luc cells subcutaneously inoculated into mice, to ensure that all mice had established and measurable tumors within 6 days of tumor cell inoculation.

Examples of reported B16F10 studies using selected other immunotherapeutic technologies:

- *Dendritic cell vaccine*: Dendritic cells pulsed with Trp2 peptide were ineffective in both prophylactic and therapeutic 1316F10 tumor models.
- *Intracellular antigen delivery:* HIV TAT protein transduction domain was conjugated to a 472 amino acid sequence from the Trp2 protein or to the Trp2 peptide, and evaluated in a prophylactic model. Both showed better tumor prevention (not therapeutic) compared to the dendritic cell vaccine. This was suggested to be the result of successful intra-cellular delivery of Trp2 by the TAT domain enabling access to the MHC class I pathway.
- *Live virus delivery*: The recombinant adeno-associated virus (rAAV) carrying Trp2 cDNA delivered 22 days before tumor challenge was unable to induce any delay in tumor growth. The addition of other adjuvants, including CpG oligonucleotides and imiquimod failed to provide additional benefit.
- *Adoptive T-cell transfer*: Utilizing Trp2 peptide specific T-cells, adoptive T-cell transfer showed no ability to inhibit tumor growth when studied in the advanced solid tumor model (inoculation of 2 x 10^5 B16F10 cells). However, in the commonly used in-vivo CTL assay to monitor T-cell activity, nearly 98% specific lysis (killing) of injected non-tumor Trp2-expressing targets occurred. This study confirmed the ability of T-cells to identify the antigen-expressing cells and also confirmed the role of the immune-suppressive tumor environment in limiting T-cell efficacy.

In PDS's published study (*Vasievich et al, Molecular Pharmaceutics, 2012, 9, 2, 261-268*), a single dose of 300nmole Versamune® with 75nmole Trp2 peptide led to a significant increase in the presence of active CD8+ T-cells (IFN-γ secreting) and inhibition of tumor growth.

The ability of Versamune® to facilitate intracellular delivery of the Trp2 peptide, and to break the immune tolerance developed by the B16F10 tumor model after only one dose, strongly suggests that Versamune® may potentially provide a superior approach to currently available technologies.

Leadership

We are led by a team of executives and directors with significant experience in drug discovery, development and commercialization. Our founder and Chief Executive Officer, or CEO, Frank Bedu-Addo, has been responsible for developing and launching products for Schering-Plough/ Merck and Liposome Company/ Elan. Our other co-founder and Chief Scientific Officer, Dr. Gregory Conn, has more than 35 years of drug-development experience, including development of antiviral and anticancer drugs through to commercialization. Other members of our senior management team have held senior positions at the National Cancer Institute Center for Cancer Research, , National Institute of Allergy and Infectious Diseases, Auxilium Pharmaceuticals and Endo\Health Solutions. In addition, our Chairman, Stephen Glover was President of Insmed Therapeutic Proteins and is the current CEO of ZyVersa Therapeutics.

We are supported by scientific leaders in the field of vaccine development and oncology. Among the distinguished experts on our Scientific Advisory Board are Dr. Mark Einstein and Professor Leaf Huang. Dr. Einstein, Professor and Chair in the Department of OB/ GYN & Women's Heath at Rutgers University Medical School is an expert in HPV-related pathogenesis, therapy and prevention of lower anogenital tract and gynecologic cancers. He is an active leader for management guidelines and translating clinical study and translational data for the World Health Organization (WHO), American Cancer Society (ACS), Society of Gynecologic Oncology (SGO) and the American College of Obstetrics and Gynecology (ACOG). Professor Leaf Huang, the scientific founder of PDS, is a Distinguished Professor of Pharmacoengineering and Molecular Pharmaceutics at the Eshelman School of Pharmacy, University of North Carolina at Chapel Hill pioneered the liposome design and manufacture of cationic lipid vector nanoparticles as a delivery system for cDNA, mRNA, siRNA, proteins and peptides for tumor growth inhibition and for vaccines in treating cancer and infectious diseases. Our Principal Investigator for the PDS0101 Head and Neck Study with KEYTRUDA for first-line treatment of recurrent/ metastasic Head and Neck Cancer is Dr. Jared Weiss, Associate Professor of Medicine, University of North Carolina Lineberger Comprehensive Cancer Center, who is an expert in head and neck thoracic oncology with a focus on immunotherapeutic approaches for these diseases. Our board member Sir Richard Sykes was the CEO and Chairman of GSK.

Research and Development Strategy

PDS focuses on developing a relatively low-risk path to successful clinical development and proof of concept ("POC"). To accomplish this, PDS formed collaborations with a number of experts in tumor biology, immunology and immuno-oncology. These partnerships have historically reduced PDS' development and clinical study expenses. Partnerships also have provided and continue to provide PDS with expert clinical collaborators, who have been intricately involved the design of PDS' upcoming Phase 2 clinical studies.

Extensive preclinical studies were performed to understand how cationic lipids interact with the immune system to prime CD8+ T-cell responses. Upon obtaining a good understanding of the immunology of the lipids and their interaction with tumor antigens, PDS optimized and evaluated PDS0101 for safety in extensive toxicology studies. Once safety was confirmed in preclinical models, PDS0101 was subsequently studied in a Phase 1 human clinical study in order to confirm safety and to confirm induction of strong HPV-specific CD8+ T-cell responses in humans.

As described herein, PDS is continuing development of the PDS0102, 0103, and 0104 programs in colorectal, melanoma, breast, lung, and prostate cancers.

Based on the successful Phase 1 human clinical study, which corroborated the preceding preclinical data, PDS established clinical supply agreements and collaborations with leaders in the field of immuno-oncology, including the NIH/NCI and Merck & Company, Inc. ("Merck").

Facilities & Manufacturing and commercial scale up

Product candidates using our Versamune® development platform are manufactured using a readily-scalable, fill-finish process with well-defined and reproducible operations. We do not own or operate cGMP compliant manufacturing facilities for the production of any of our product candidates and we do not have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturing organizations ("CMOs") to produce the amounts of our product candidates necessary for our preclinical research and clinical studies. As part of the manufacture and design process for our product candidates, we rely on internal, scientific and manufacturing know-how and trade secrets and the know-how and trade secrets of third-party manufacturers. We currently employ internal resources to manage our manufacturing contractors.

PDS research and development activities are located at the Princeton Innovation Center BioLabs, 303A College Road East, Princeton, NJ 08540, which provides first-rate development facilities for biotech companies. All animal toxicology and efficacy testing are done via third party contracts and collaborations in order to provide maximum flexibility and to minimize operational costs and overhead. This approach allows for independent validation of our data, and we believe it has historically been a cost-efficient way to progress our development programs.

We do not intend to incur the costs of building, staffing and maintaining manufacturing facilities in the near term. Our management team has extensive formulation, manufacturing and operations expertise, including past senior executive management roles in contract drug development and manufacturing. The team plans to utilize its expertise and knowledge to identify suitable contract manufacturers who will be capable of efficiently manufacturing PDS's products.

Regulatory Pathway

For our lead product candidate, PDS0101, the next step in the product development process will be Phase 2 clinical trials. This process is described further under " **U.S. Product Development Process**." The final protocols for the PDS0101 study for treatment of recurrent metastatic head and neck cancer and the final protocol for the PDS0101 study with the NCI have been submitted to the FDA. For PDS0101 we plan to submit a Chemistry, Manufacturing, and Controls (CMC) amendment to our Investigational New Drug (IND) application, related to PDS's planned Phase 2 studies with PDS0101 to the FDA in 1H 2020. This is to conform to the FDA electronic Common Technical Document_(eCTD) format requirement and submission of the CGMP material that will be used in the Phase 2 trials.

If Phase 2 clinical trials are initiated and completed and support further development, under standard FDA processes we would then need to complete Phase 3 clinical trials and gather other necessary application data and information for PDS0101 to seek marketing authorization.

PDS anticipates that it would seek marketing authorization from the U.S. FDA for its product candidates through the Biologics License Application (BLA) pathway, under Section 351(a) of the Public Health Service Act (PHSA). This process and the requirements are described further under "**U.S. Product Development Process.**"

Intellectual Property

PATENTS

We seek to maintain high barriers to entry around our product candidates and the markets in which they are utilized by using a multiple layered approach to our patents, patent applications, and substantial know-how and trade secrets related to the Versamune® platform. PDS strives to protect and enhance the proprietary technology, inventions and improvements that are commercially important to its business, including seeking, maintaining, and defending patent rights. PDS also relies on trade secrets relating to its platform and on know-how, continuing technological innovation to develop, strengthen and maintain its proprietary position in the vaccine field. In addition, PDS relies on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. PDS also utilizes trademark protection for its company name, and expects to do so for products and/or services as they are marketed.

PDS has developed numerous patents and patent applications and owns substantial know-how and trade secrets related to its Versamune ® platform. As of December 31, 2019, PDS holds four (4) U.S. patents with granted claims directed to its platform technology and six (6) pending patent applications. These issued patents will expire in 2025, 2031, 2031 and 2033. Should the more recently submitted patents currently in prosecution be issued, these will expire in 2033 through 2037 assuming no patent term extensions are granted. As of December 31, 2019, PDS holds twenty-two (22) issued foreign patents and thirty-three (33) pending foreign patent application, most of which are issued in multiple countries including Europe, Japan and Australia, and all of which cover compositions of matter and methods of use related to its platform technology. These issued patents will expire in 2031-2034, or later if patent term extension applies.

The United States Patent and Trademark Office (USPTO) recently granted Patent No. 15/702,063 titled "Stimulation of an Immune Response by Enantiomers of Cationic Lipids." This patent provides protection for compositions of matter and specifically the immune activating compositions containing Versamune®, the immunologically active enantiomer of the cationic lipid 1,2-dieleoyl-3-trimethyl-ammonium-propane (R-DOTAP) and a specific antigen.

Licensed Patents

Licensed Patent Families 1 and 2 cover the Versamune ®-based product candidates, as they are directed to the currently utilized Versamune ® ingredient, (R)-DOTAP and its crystal forms, manufacturing methods, and pharmaceutical compositions using the compounds. PDS Biotechnology has an exclusive worldwide license from Merck & Cie to Licensed Patent Families 1 and 2, which are owned by Merck Patent GmbH, for use in the Company's immunotherapy compositions and immunotherapies. Merck & Cie has informed the Company that it has rights to license these patent families through an intra-company agreement with Merck Patent GmbH.

Licensed Patent Families 1-2 (which cover (R)-DOTAP compositions and crystal forms and methods of use) are also of significance to the Company's future commercial endeavors in using (R)-DOTAP to develop additional immunotherapies and immune modulators.

Licensed Patent Families 3 and 4 are licensed from the US government and are directed to mucin-1 ("MUC-1") antigens to be used by the Company in future cationic lipid immunotherapy or vaccine products. Such immunotherapies can be used for treating a range of cancers, including colon, breast, ovarian and lung cancers.

Trade Secrets and Other Proprietary Information

In contrast to patent protection or regulatory exclusivities, trade secret protection is a form of intellectual property that does not require disclosure of the subject information as part of the process, but instead depends on maintaining the subject information as strictly confidential. Companies may in some circumstances rely on trade secrets to protect certain aspects of their proprietary know-how and technological advances, especially where they do not believe patent protection is appropriate or obtainable. Trade secret protection depends in part on confidentiality agreements with employees, consultants, outside scientific collaborators, sponsored researchers and other advisors that prohibit disclosure of designated proprietary information. Trade secrets can be difficult to protect. Confidentiality agreements may not succeed in preventing a person or parties from actually disclosing confidential information, and in that event the rights of the trade secret holder are subject to the viability of an adequate remedy at law, typically under state law modeled on the Uniform Trade Secrets Protection Act, to stop, mitigate or compensate for the unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of the proprietary rights. Finally, there is always at least some risk that others may independently discover the trade secrets and proprietary information.

Material License Agreements and Research and Development Agreements

Patent License Agreement with National Institutes of Health.

Effective January 5, 2015, PDS entered into a Patent License Agreement (the "Patent License Agreement") as Amended by First Amendment to Patent License Agreement ("First Amendment") of August 5, 2015, with the National Institutes of Health ("NIH") an agency within the Department of Health and Human Services ("HHS"), pursuant to which NIH granted PDS a nonexclusive license to certain patent rights for the development of a therapeutic cancer vaccine specifically in combination with PDS's proprietary Versamune® technology for ovarian, breast, colon and lung cancers. The Patent License Agreement expires when the last licensed patent expires, if the Patent License Agreement is not terminated prior to that date. NIH may terminate the Patent License Agreement if PDS is in default in the performance of any material obligation under the Patent License Agreement. PDS may unilaterally terminate the Patent License Agreement in any country or territory upon sixty (60) days written notice.

Under the Patent License Agreement and First Amendment PDS agreed to pay NIH: (a) a noncreditable, nonrefundable royalty in the amount of $30,000 upon execution of the Patent License Agreement; (b) a noncreditable, nonrefundable royalty in the amount of $60,000 upon execution of the First Amendment to Patent License Agreement (c) a nonrefundable minimum annual royalty of $5,000; (d) earned royalties of two percent (2%) on net sales, reducible by a half percent (0.5%) for any earned royalties PDS must pay to third parties; (e) benchmark royalties as follows: (i) $25,000 upon successful completion of each Phase 2 Clinical Studies of a licensed product for breast, colon, lung or ovarian cancer within each licensed territory; (ii) $50,000 upon initiation of the first Phase 3 Clinical Study of a licensed product for breast, colon, lung or ovarian cancer within each licensed territory; (iii) $750,000 upon the first commercial sale in the licensed territory utilizing and/or directed to licensed product(s) and/or licensed process(es) within the licensed patent rights for breast, colon, lung or ovarian cancer; and (f) additional sublicensing royalties for each sublicense required to be approved by NIH of four percent (4%) on the fair market value of any consideration received for granting such sublicense.

DOTAP Chloride Enantiomer License Agreement with Merck Eprova AG.

Effective November 1, 2008, PDS entered into a DOTAP Chloride Enantiomer License (the "DOTAP License Agreement") with Merck Eprova AG ("EPRO"), pursuant to which PDS obtained an exclusive license from EPRO technology to undertake development of products relating to the R-enantiomer and S-enantiomer of DOTAP Chloride for worldwide commercialization in a composition and method of inducing an immune response in a subject by administering at least one cationic lipid with or without an antigen. The DOTAP License Agreement expires on a licensed product-by-licensed product and country-by-country basis until the expiration of the obligation to pay royalties applicable to such licensed product in such country. PDS has the right to unilaterally terminate the DOTAP License Agreement (in its entirety or on a licensed product-by-licensed product or country-by-country basis) at any time for any reason upon prior written notice. Upon the reverse merger and according the agreement under the "Compensation due to Assignability" provisions PDS paid a one-time royalty of CHF 100,00 as a result of the reverse merger between PDS and Edge Therapeutics.

Cooperative Research and Development Agreement for Intramural-PHS Clinical Research with The U.S. Department of Health and Human Services.

Effective February 2, 2016, PDS entered into a Cooperative Research and Development Agreement (the " *CRADA*") with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute ("*NCI*"), pursuant to which the parties agreed to perform certain research and development activities as defined by the exhibited Research Plan. The principal goal of the CRADA is to determine whether PDS's Versamune® immunotherapeutic technology will be effective for enhancing delivery of cancer vaccines or viral vaccines or other immunotherapies developed by the Vaccine Branch, Center for Cancer Research, NCI, in mouse models and in human clinical studies. The CRADA provides for development, testing and studies to be conducted in conjunction with the Vaccine Branch involving Versamune® and Multi-epitope (ME) T cell receptor gamma alternate reading frame protein peptide (TARP) to develop a treatment for prostate cancer using autologous dendritic cells and co- administered locally with ME TARP peptides co-formulated with Versamune® immunotherapeutic technology in a non-cellular vaccine platform.

The term of the CRADA is five (5) years, starting February 2, 2016. Pursuant to Appendix A, PDS agreed to provide up to $1,000,000 but no less than $500,000 during the first year of the CRADA and up to $1,000,000 but no less than $750,000 per year for the remaining years of the CRADA for NCI to use in connection with acquiring technical, statistical, and administrative support for the clinical research activities, as well as to pay for supplies and travel expenses and, upon consent of the parties, to acquire support for a postdoctoral research fellow to conduct additional preclinical studies. The CRADA may be terminated by either party at any time by mutual written consent. Either party may unilaterally terminate the CRADA at any time by providing sixty (60) days written notice. If PDS terminates prior to the completion of all approved or active study protocol(s) pursuant to the CRADA, PDS must supply enough study test product to complete these study protocol(s) unless termination is for safety reasons. If the CRADA is mutually or unilaterally terminated by PDS before its expiration, PDS must pay non-cancellable obligations for personnel for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever is sooner. If PDS suspends development on the test article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, NCI may continue development. In such event, PDS must transfer all information necessary to enable NCI to contract for the manufacture of the test article and grant NCI a nonexclusive, irrevocable, worldwide, paid-up license regarding same.

Cost Reimbursement Agreement with University of Kentucky Research Foundation - I.

Effective November 1, 2015, PDS entered into an annual Research Agreement (the "Cost Reimbursement Agreement") with the University of Kentucky Research Foundation ("UKRF"), pursuant to which UKRF agreed to test PDS's preclinical and clinical-stage formulations based on HPV, TARP, MUC-1, Melanoma antigens as specified more fully in the statement of work. The Cost Reimbursement Agreement has been renewed annually, and was renewed on July 1, 2019 for an anticipated cost of $333,496. The agreement terminates on June 30, 2020 unless extended by written mutual agreement of parties or is terminated by one of the parties. Either party may terminate the Cost Reimbursement Agreement for any reason with thirty (30) days written notice.

Cost Reimbursement and Sponsored Agreement with University of Kentucky Research Foundation - II.

Effective November 1, 2015, PDS entered into an annual Research Agreement (the "Cost Reimbursement Agreement") with the University of Kentucky Research Foundation ("UKRF"), pursuant to which UKRF agreed to test PDS's preclinical and clinical-stage formulations based on HPV, TARP, MUC-1, Melanoma antigens as specified more fully in the statement of work. The Cost Reimbursement Agreement has been renewed annually, and was renewed on July 1, 2019 for an anticipated cost of $12,963. The agreement terminates on June 30, 2020 unless extended by written mutual agreement of parties or is terminated by one of the parties. Either party may terminate the Cost Reimbursement Agreement for any reason with thirty (30) days written notice.

Clinical Trial Collaboration and Supply Agreement with MSD International GmbH.

Effective May 19, 2017, PDS entered into a Clinical Trial Collaboration and Supply Agreement (the "CTCSA") with MSD International GmbH ("Merck") pursuant to which PDS and Merck agreed to collaborate in a Phase 2 clinical study to evaluate the safety, and preliminary efficacy of the concomitant and/or sequenced administration of the combination of a Merck compound (i.e., pembrolizumab, a humanized anti-human PD-1 monoclonal antibody) and a PDS compound (i.e., PDS0101, a cationic lipid-based therapeutic vaccine combining HPV peptides) in treatment of patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV 16) infection. The term of the CTCSA commenced on May 19, 2017 and shall continue until the earlier of (i) delivery of the final study report and (ii) Study Completion (i.e., upon database lock of the Study results), or until terminated by either party. In the event the CTCSA is terminated by Merck upon a material breach by PDS, PDS must reimburse Merck for its direct manufacturing costs, such as manufacturing fees, raw materials, direct labor, freight and duty, factory overhead costs and its indirect manufacturing costs, such as allocations of indirect factory overhead and site support costs. This agreement was amended on October 28, 2019 to reflect the study will be for first in line treatment of disease.

On October 28, 2019, PDS entered into an amendment to the clinical trial collaboration agreement with Merck to evaluate the combination of PDS's lead Versamune®-based immunotherapy, PDS0101, with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase II clinical study. The planned clinical study will now evaluate the efficacy and safety of the combination as a first-line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection and is expected to be initiated in the first half of 2020. The modification to the clinical study design to evaluate PDS0101 in combination with KEYTRUDA® as first-line treatment comes as a result of Merck's approval by the FDA on June 10, 2019 for first line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) using KEYTRUDA® in combination with platinum and fluorouracil (FU) for all patients and as a single agent for patients whose tumors express PD-L1 as determined by an FDA-approved test.

Other Research and Development Agreements

Cooperative Research and Development Agreement for Intramural-PHS Clinical Research with The U.S. Department of Health and Human Services.

Effective April 22, 2019, PDS entered into a Cooperative Research and Development Agreement (the " *CRADA*") with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute ("*NCI*"), pursuant to which the parties agreed to perform certain research and development activities as defined by the exhibited Research Plan.. Under the agreement, PDS will collaborate with the NCI's Genitourinary Malignancies Branch (GMB) and Laboratory of Tumor Immunology and Biology (LTIB) with plans to conduct a Phase 2 clinical study evaluating PDS0101 with novel immune-modulating agents M7824 and NHS-IL12 being studied at NCI as part of a CRADA with EMD Serono (Merck KGaA). The phase 2 clinical study is anticipated to start in the first quarter of 2020. The CRADA also involves preclinical evaluation of PDS0101 in combination with other therapeutic modalities upon the mutual agreement of both parties.

The term of the CRADA is five (5) years, starting April 22, 2019. Pursuant to Appendix A, PDS agreed to provide $110,000 annually, the first payment of which is to be made on the first anniversary the of the CRADA Effective date or upon the initiation of a Phase II clinical study as the NIH Clinical Center, whichever comes first for NCI to use in connection with acquiring technical, statistical, and administrative support for the clinical research activities, as well as to pay for supplies and travel expenses and infrastructure costs. The CRADA may be terminated by either party at any time by mutual written consent. Either party may unilaterally terminate the CRADA at any time by providing sixty (60) days written notice. If PDS terminates prior to the completion of all approved or active study protocol(s) pursuant to the CRADA, PDS must supply enough study test product to complete these study protocol(s) unless termination is for safety reasons. If the CRADA is mutually or unilaterally terminated by PDS before its expiration, PDS must pay non-cancellable obligations for personnel for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever is sooner. If PDS suspends development on the test article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, NCI may continue development. In such event, PDS must transfer all information necessary to enable NCI to contract for the manufacture of the test article and grant NCI a nonexclusive, irrevocable, worldwide, paid-up license regarding same.

Amended and Restated Material Transfer Agreement with Farmacore Biotechnology

On December 4, 2019 PDS entered into an Amended and Restated Material Transfer Agreement with Farmacore Biotechnology to develop a novel tuberculosis (TB) immunotherapy based on Farmacore's proprietary TB antigens and Versamune®. A prior material transfer agreement under which preliminary work commenced was Amended and Restated due to promising early pre- clinical results and to progress to the next development phase. PDS will undertake product development and Farmacore will conduct pre-clinical studies to evaluate the efficacy of the product. The term of the agreement extends until the end of the product testing period and may be terminated at any time by either party with 30 days' notice.

Competition

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While PDS believes that the Versamune® platform provides it with competitive advantages, PDS faces competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that PDS may commercialize will have to compete with existing products and therapies as well as new products and immunotherapies that may become available in the future.

PDS anticipates that it will face intense and increasing competition as new immunotherapies enter the market and advanced technologies become available. PDS expects any products that it develops and commercializes to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors. PDS's competitors may obtain FDA or other regulatory approval for their products more rapidly than it may obtain approval for its products, which could result in PDS's competitors establishing a strong market position before it is able to enter the market. In addition, the ability of PDS to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

There is currently no approved HPV therapeutic product available for sale globally. PDS has performed an evaluation of HPV therapeutic products in development and considers the products utilizing effective antigen delivery systems to the dendritic cells to be its closest competitors. PDS believes its top clinical-stage competitors include Advaxis, Transgene, ISA Pharmaceuticals, and Inovio. PDS also has considered companies developing closely related products as competitors, including Etubics, Vaccibody, Admedus, Cel-Sci, Neo-ImmuneTech, Kite Pharma, Immune Design, Dynavax, Bavarian Nordic, Seattle Genetics, and Selecta Biosciences.

Government Regulation and Product Approval

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those PDS is developing. PDS's product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, its activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates biological drug products under the Federal Food, Drug and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to certain other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-approval, may subject an applicant to administrative or judicial action. FDA decisions or enforcement actions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on PDS.

The process required by the FDA before a biological drug product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practice regulations, or GLP, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an investigational new drug application, or an IND, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies according to the FDA's regulations commonly referred to as good clinical practice, or GCP, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency/efficacy of the product that is the subject of the BLA based on results of nonclinical testing and clinical studies (including among other things clinical data, chemistry, and manufacturing and controls (CMC) data);
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- pre-approval inspection by the FDA of the sponsor (or any third party service providers) relative to oversight of clinical studies, clinical trial sites that generated the data in support of the BLA, and any manufacturing facilities; and
- FDA review and approval, or licensure, of the BLA.

Before testing any product candidate in humans, the product enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The results of preclinical studies and early clinical studies of product candidates with small patient populations may not be predictive of the results of later-stage clinical studies or the results once the applicable clinical studies are completed. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical studies and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, PDS cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the biological product candidate to volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection (for example, inclusion and exclusion criteria), and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND and also require IRB approval. Clinical trials must be conducted and monitored in accordance with the FDA law including GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in seriously ill subjects. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical studies may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical studies.

- Phase 3. Clinical studies, which must be adequate and well-controlled, are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population generally at geographically dispersed clinical trial sites. These clinical studies are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Although these are the typical phases of progression, and characteristics of the phases of a clinical development program, certain expedited programs allow for variations that could support a marketing application based on surrogate endpoints, intermediate clinical endpoints, or single-arm as opposed to comparative or placebo-controlled studies (for example, FDA could rely on well-controlled Phase 2 studies for evidence of effectiveness under certain circumstances).

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up, or to gain other information about the product.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators of potential safety risks, from clinical trials or any other source, including for serious and unexpected adverse events and serious and unexpected suspected adverse reactions, any findings from other studies suggesting a significant risk in humans exposed to the drug, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but no later than within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the sponsor or its data safety monitoring board, or DSMB, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website, and other jurisdictions have similar laws that may apply.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant application fee. For approved drugs, including BLA-licensed biological products, PDUFA also imposes an annual PDUFA program fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on BLAs for products designated as orphan drugs, unless the application for the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, and applications for new molecular entities and original BLAs are generally discussed at advisory committee meetings unless the FDA determines that this type of consultation is not needed under the circumstances. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it is satisfied that the manufacturing establishments and processes supporting the BLA meet the appropriate requirements and comply with the applicable regulations (including cGMP requirements and adequate assurance for consistent commercial production of the product within required specifications). Additionally, before approving a BLA, the FDA will typically conduct a pre-approval inspection of regulated participants in clinical trials (for example, the sponsor, investigators responsible for specific sites, and CROs) to assure that the clinical trials were conducted in compliance with the IND and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than PDS interprets the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical studies, sometimes referred to as Phase 4 clinical studies, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA for a new indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Post-Approval Requirements

Any products for which PDS receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses or consistent with the approved labeling, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential False Claims Act exposure. Further, the FDA has not materially changed its position on off-label promotion following legal setbacks on First Amendment grounds and the DOJ has consistently asserted in FCA briefings that "speech that serves as a conduit for violations of the law is not constitutionally protected."

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The Drug Supply Chain Security Act, or DSCSA imposes obligations on manufacturers of prescription biopharmaceutical products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts certain previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act, or PDMA. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription biopharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years through 2023, and subject companies will need to continue their implementation efforts. Many states still have in place licensure and other requirements for manufacturers and distributors of drugs. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of its product candidates under development.

Regulatory Exclusivities Applicable to Biologics and Related Matters

Abbreviated Licensure Pathway for Biosimilars: The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") amended the PHSA to create an abbreviated approval pathway for "biosimilar" biologics, that is, those shown to be highly similar to an already-FDA-licensed reference biologic. The abbreviated approval process for biosimilars under the BPCIA is similar in concept to the Abbreviated New Drug Application ("ANDA") for generic small molecule drugs established by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman") amendments to the FDCA. As with Hatch-Waxman, the goal of the BPCIA was to increase access to lower-priced versions of drugs, while balancing the need to continue incentivizing innovation in drug development. Biosimilarity is defined to mean that the proposed biologic is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. Further, a biosimilar may be determined to be "interchangeable" with the reference product, in which case the biosimilar may be substituted for the reference product under state substitution laws, similar to the way generic small molecule drugs are substituted. The higher standard of interchangeability requires a showing that the biosimilar is expect to produce the same clinical result as the reference biologic in any given patient, and further that the risk to the patient in terms of safety, purity, and/or potency pf switching between the biosimilar and the reference product is no more than using the reference product without switching.

Regulatory Exclusivities Applicable to Biologics Under the BPCIA: The BPCIA established certain regulatory exclusivities that provide reference biologics with prescribed periods of time during which competing biosimilars or interchangeable biosimilars may not be approved or may not be marketed. Once its BLA is approved ("date of first licensure) the reference biologic is entitled to a period of four years after its date of first licensure during which time FDA is prohibited from accepting a marketing application that would seek approval of any products that are biosimilar to the branded product. In addition, the reference biologic is entitled to a period of 12 years after its date of first licensure during which time FDA is prohibited from approving marketing applications for any products that are biosimilar to the branded product. In addition, the first interchangeable biosimilar may be entitled to a period of one year after its date of first licensure, or other periods keyed to the outcome of patent litigation if instituted, during which FDA is prohibited from finding that any other biosimilars are interchangeable to the same reference biologic. The reference biologic may also be entitled to regulatory exclusivity under other statutory provisions that apply to biologics and small molecule drugs.

Orphan Drug Exclusivity: Under the Orphan Drug Act, the FDA may grant orphan drug designation to biological products indicated for a rare disease or condition, generally a disease or condition that affects fewer than 200,000 individuals in the United States, or in the alternative there is no reasonable expectation that the cost of developing and making a product available in the United States for such disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the biological product and its potential orphan use are disclosed publicly by the FDA. The first BLA sponsor to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a period of 12 years after its date of first licensure during which time FDA is prohibited from approving marketing applications for any products that are biosimilar to the branded product. There is an exception in certain limited circumstances, such as for a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same biological product for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and a waiver of the BLA user fee.

Pediatric Study Requirements and Pediatric Exclusivity: Under the Best Pharmaceuticals for Children Act (BPCA), a sponsor qualifies for "pediatric exclusivity" if it complies with a Written Request (WR) issued by FDA for pediatric studies. The sponsor may apply to FDA to issue a WR. Pediatric exclusivity operates by adding six months of exclusivity on to the end of the latest-expiring form of exclusivity, and may apply to patent rights or to FDA regulatory exclusivities. To qualify for pediatric exclusivity, at least one of those rights must still be currently in force at the time FDA approves the pediatric studies.

Patent Term Extensions: Patents have a limited lifespan. In most countries, including the U.S., the standard expiration of a patent is 20 years from the effective filing date. Various extensions of patent terms may be available in certain circumstances, for example where there are delays in obtaining FDA regulatory approvals that result in a reduction of the period of time during which we could market a product under patent protection. In the U.S., such possible extensions include those permitted under Hatch-Waxman, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials, and FDA must agree with our calculation of the time lost in regulatory review.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, PDS's activities are potentially subject to regulation, either directly or indirectly, by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General (OIG), the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the criminal provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the federal Anti-Kickback Statute, the federal false claims laws, the physician payment transparency laws, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. PDS's practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. The lack of uniform court interpretation of the Anti-Kickback Statute combined with emerging, novel enforcement theories, makes compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a per se false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

The Criminal Healthcare Fraud statute, 18 U.S.C. § 1347 prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The *qui tam* provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government, whether directly or indirectly. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have enacted similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor, even extending to self-pay items and services.

PDS may be subject to data privacy and security regulations by both the federal government and the states in which it conducts its business. We are not a covered entity under HIPAA and have not functioned as a business associate under HIPAA that would cause the HIPAA Security Rule and provisions of the Privacy Rule to apply directly to us as a business associate. To the extent that we ever function in a business associate capacity, HIPAA, as amended by the HITECH Act, and its respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Following enactment of the HITECH Act, HIPAA's privacy and security standards now directly apply to business associates of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, and may apply more broadly thus complicating compliance efforts (for example, California recently enacted legislation — the California Consumer Privacy Act, or CCPA — which went into effect on January 1, 2020 and among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information, and creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach; the California Attorney General will issue final regulations, and although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context, and it remains unclear what language the final Attorney General regulations will contain or how the statute and the regulations will be interpreted.)

Even for entities that are not deemed "covered entities" or "business associates" under HIPAA, according to the United States Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 USC § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC's authority under Section 5 is concurrent with HIPAA's jurisdiction and with any action taken under state law.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". In 2022 the Sunshine Act will be extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, PDS must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical studies and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of PDS's activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between pharmaceutical companies and providers and patients, which has led to a number of investigations, prosecutions, convictions and settlements in the industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business, even if investigators ultimately find that no violation has occurred.

If PDS operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, PDS may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties; damages; fines; disgorgement; exclusion from participation in government programs, such as Medicare and Medicaid; injunctions; private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow it to enter into government contracts; contractual damages; reputational harm; administrative burdens; diminished profits and future earnings; and the curtailment or restructuring of its operations; any of which could adversely affect PDS's ability to operate its business and its results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which PDS obtains regulatory approval. In the United States and markets in other countries, sales of any products for which PDS receives regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. PDS may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of its tablet product candidates, in addition to the costs required to obtain the FDA approvals. PDS's product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable PDS to maintain price levels sufficient to realize an appropriate return on its investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which it receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement, or require onerous prior approvals or other restricted access. In addition, emphasis on managed care in the United States has increased and PDS expects the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which PDS receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In recent years, there have been numerous initiatives on the federal and state levels in the United States for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. PDS anticipates that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that PDS receives for any approved product, if covered, and could seriously harm its business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent PDS from being able to generate revenue, attain profitability or commercialize its product candidates. In addition, it is possible that there will be further legislation or regulation that could harm its business, financial condition and results of operations.

The Patient Protection and Affordable Care Act (ACA) which was signed into law in the United States in March 2010, contained several provisions affecting the pharmaceutical industry:

- the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services, or HHS, as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients;
- in order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer;
- the ACA imposed a requirement on manufacturers of branded drugs to provide a 70% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the donut hole);
- the ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- the ACA implemented the Physician Payments Sunshine Act;
- the ACA requires annual reporting of drug samples that manufacturers and distributors provide to physicians;
- the ACA expanded healthcare fraud and abuse laws in the United States, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- the ACA established a licensing framework for follow-on biologics; and
- the ACA established the new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with the funding for such research.

The Trump Administration and the Congressional Republicans have proposed several efforts to repeal and replace the ACA. President Trump has also signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, on December 15, 2019, a federal district court in Texas struck down the ACA in its entirety, finding that the TCJA renders the individual mandate unconstitutional. The judge further concluded in *Texas v. Azar* that since the individual mandate is "essential" to the ACA, it could not be severed from the rest of the ACA and therefore, the entire ACA was unconstitutional. Despite its decision, however, the court did not issue an injunction and therefore, immediate compliance is not required. In addition, the Trump Administration announced that it will continue to administer the law until a formal decision is made by the U.S. Supreme Court. The Supreme Court has not yet announced when or whether it will hear a challenge in *Texas v. United States*, though it is highly anticipated that it will do so next term (beginning October 2020). Apart from *Texas v. United States*, ACA litigation continues across the country in district and appellate courts, and before the Supreme Court. The Supreme Court will issue at least two ACA-related decisions before the end of its current term: one on the risk corridors program (*Maine Community Health Options v. United States*) and the other on religious or moral exemptions to the contraceptive mandate (*Trump v. Pennsylvania* and *Little Sisters of the Poor v. Pennsylvania*). Both decisions are expected before July 2020. It is unclear how the eventual decisions from the Supreme Court and the various other courts across the country to repeal and replace the ACA will impact the ACA and our business. It is also unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business, particularly entering an election year.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies seeking information about pricing practices in connection with an investigation into pricing practices being conducted by the U.S. Department of Justice. Several state attorneys general also have commenced drug pricing investigations and filed lawsuits against pharmaceutical companies, and the U.S. Senate has publicly investigated a number of pharmaceutical companies relating to price increases and pricing practices. Proposed legislation has been designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Recent federal budget proposals have included measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The U.S. Congress and the Trump Administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers (PBMs) in the supply chain. Drug pricing is and will remain a key bipartisan issue in the coming year. If drug pricing reform is not meaningfully addressed before the 2020 election, policies to be pursued in the future may be more aggressive, regardless of which party controls the White House. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The boom in state laws targeting drug pricing is unprecedented and the requirements are not uniform from state to state, creating additional compliance and commercialization challenges for manufacturers. If PDS is able to obtain marketing approval for one or more of our products, our revenue and future profitability could be negatively affected if these or other inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of any products for which we obtain marketing approval.

Foreign Regulation

In order to market any product outside of the United States, PDS would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical studies, marketing authorization, commercial sales and distribution of its products. Whether or not PDS obtains FDA approval for a product, it would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical studies or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Employees

PDS's management team possesses considerable experience in drug development research, manufacturing, clinical development and regulatory matters. PDS' semi-virtual operating strategy of collaborating with scientific and clinical experts in cancer immunology, tumor immunology and gynecological oncology provides additional considerable experience in immunotherapy development, clinical design and execution. PDS has no collective bargaining agreements with its employees and it has not experienced any work stop pages.

Legal Proceedings

From time to time, PDS may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Litigation, regardless of the outcome, could have an adverse impact on PDS because of defense and settlement costs, diversion of management resources and other factors. PDS is not currently a party to any legal proceedings, the adverse outcome of which, in PDS's management's opinion, individually or in the aggregate, would have a material adverse effect on PDS's results of operations or financial position.

ITEM 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes appearing elsewhere in this Annual Report, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and our future prospects would likely be materially and adversely affected. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have never generated any product revenue.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were founded in December 2005, and our operations to date have been limited to organizing our company and developing the Versamune® platform and related immunotherapy product candidates that incorporate the technology of our Versamune® platform. We have not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured Versamune® at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our Versamune® products. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing immunotherapies.

Our ability to generate revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our Versamune ®-based products for the treatment of HPV-related cancers, or PDS0101, and/or complete the development of our PDS0102, PDS0103, or PDS0104 products, or, collectively with PDS0101, the Versamune® Products, for treatment of non-HPV-related cancers and other infectious diseases and to obtain the necessary regulatory approvals. We have never generated any product revenue and have no immunotherapy candidate in late-stage clinical development or approved for commercial sale.

Even if we receive regulatory approval for the sale of the Versamune ® Products, we do not know when we will begin to generate revenue from PDS0101, if at all. Our ability to generate revenue depends on a number of factors, including our ability to:

- set an acceptable price for Versamune®-based immunotherapy candidates, including the Versamune® Products, and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of PDS0101 and other Versamune ® Products at acceptable cost levels;
- achieve broad market acceptance of PDS0101 and other Versamune ® Products in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of PDS0101 and other Versamune ® Products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with immunotherapy development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if PDS0101 is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for PDS0101 and other Versamune® Products. If we cannot successfully execute on any of the factors listed above, our business may not succeed, and your investment will be adversely affected.

We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have never generated any product revenues and expect to continue to incur substantial and increasing losses as we continue to develop PDS0101 and other Versamune ® based Products. PDS0101 has not been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have PDS0101 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize PDS0101 or other Versamune® Products. If we successfully obtain regulatory approval to market PDS0101, our revenues will be dependent, in part, upon, the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets for the approved indication, and the price at which we can offer PDS0101. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of PDS0101, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable the market price of our common stock and our ability to raise capital and continue operations will be adversely affected.

We expect research and development expenses to increase significantly for PDS0101 and other Versamune ® Products. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize PDS0101. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. As of December 31, 2019, we had an accumulated deficit of $26.6 million.

We are dependent on the success of PDS0101, which is still in early-stage clinical development, and if PDS0101 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

PDS0101 is only in early clinical development, and as a consequence, it is too early to determine whether the Versamune ® Products will ever be approved for commercial sale or marketable. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to PDS0101 and other Versamune® Products. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of PDS0101. PDS0101 may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of PDS0101 is and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market PDS0101 in the United States until it receives approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until it receives the requisite approval from such countries. To date, we have only completed Phase 1/2A clinical trials for certain applications of PDS0101. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of PDS0101 for many reasons, including:

- we may not be able to demonstrate that PDS0101 is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1/2A clinical trials of PDS0101 satisfy the FDA's requirements and may require us to conduct additional testing;
- the results of our future clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of PDS0101 outweigh the safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the FDA may identify deficiencies in our manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of PDS0101.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize PDS0101. Even with our current cash reserves, we will require substantial additional capital to complete the development and potential commercialization of PDS0101 and the development of other Versamune® Products. If we are unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, if at all, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

Based upon our current operating plan, we believe that our cash reserves will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this report. Our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of PDS0101 is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize PDS0101 on our own; and
- the initiation, progress, timing and results of the commercialization of PDS0101, if approved, for commercial sale.

Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of PDS0101 or potentially discontinue operations. In July 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, at our discretion, Aspire Capital is committed to purchase up to an aggregate of $20.0 million of shares of our common stock, or the Purchased Shares, over the 30-month term of the Aspire Purchase Agreement. We may sell an aggregate of 1,034,979 shares of our common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. We may sell additional shares of our common stock above the 19.99% limit provided that (i) we obtain stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of our common stock on July 26, 2019. On July 29, 2019, we issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. As of December 31, 2019, no Purchase Shares have been sold to Aspire Capital under the Aspire Purchase Agreement. Further, our use of the Aspire Purchase Agreement is subject to certain additional limitations set forth elsewhere in this report. As such, our ability to use the Aspire Purchase Agreement to raise additional capital is uncertain.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, including through the Aspire Purchase Agreement (assuming all conditions for the issuance of the Purchased Shares under the Aspire Purchase Agreement are satisfied), debt financings, strategic alliances and license and development agreements in connection with any collaborations. In February 2020, we completed an underwritten public offering, in which we sold 10,000,000 shares of common stock at a public offering price of $1.30 per share. The shares sold included 769,230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price. We received gross proceeds of approximately $13 million and net proceeds of approximately $11.9 million after deducting underwriting discounts and commissions. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or Versamune® Products or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our PDS0101 development or future commercialization efforts or grant rights to develop and market other Versamune® Products that we would otherwise develop and market.

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

We are highly dependent on our executive officers and the other principal members of the executive and scientific teams, particularly our President and Chief Executive Officer, Dr. Frank K. Bedu-Addo, our Chief Medical Officer, Dr. Lauren Wood, and our Chief Scientific Officer, Dr. Gregory L. Conn. The employment of our executive officers are at-will and our executive officers may terminate their employment at any time, subject to applicable notice requirements. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain "key person" insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, and operational personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. we also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to the company, our business may be harmed

If we fail to obtain or maintain adequate coverage and reimbursement for PDS0101, our ability to generate revenue could be limited.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of PDS0101 that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of PDS0101 will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize PDS0101. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow it to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price PDS0101 on less favorable terms than we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of PDS0101 to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for PDS0101. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for PDS0101. We expect to experience pricing pressures in connection with the sale of PDS0101 due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint may require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations.

Our future financial performance and our ability to commercialize PDS0101 and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, 2019, we had 15 employees and 5 consultants. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. Additionally, as part of our material weakness remediation plan, we intend to hire a new Chief Financial Officer and accounting and finance personnel as needed. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of PDS0101. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what it has to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop PDS0101 and our business will be limited.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business and operations would suffer in the event of system failures.

Our computer systems and those of our service providers, including our CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of PDS0101 could be delayed.

Our failure to comply with international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the EU Data Protection Directive, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Our failure to comply with state and/or national data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act, or HIPAA, and associated regulations. For example, California recently enacted legislation - the California Consumer Privacy Act, or CCPA - which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it remains unclear what language the final Attorney General regulations will contain, or how the statute and regulations will be interpreted.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We expect to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or Dodd-Frank Act, the SEC, and Nasdaq. These rules and regulations are expected to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. Increases in costs incurred as a result of becoming a publicly traded company may adversely affect our operating results and financial condition.

We have identified material weaknesses in our internal control over financial reporting, and if we are unable to remediate such material weaknesses and to maintain effective internal control over financial reporting in the future, there could be an elevated possibility of a material misstatement, and such a misstatement could cause investors to lose confidence in our financial statements, which could have a material adverse effect on our stock price.

As disclosed in Item 9A of this report, we have identified material weaknesses as of December 31, 2019 in our internal control over financial reporting.

Our management team has taken action to begin to remediate the material weaknesses, primarily through improved processes, policies, training and skilled personnel, but we cannot be certain when the remediation will be completed. If we fail to fully remediate the material weaknesses or fail to maintain effective internal controls, it could result in a material misstatement of our financial statements, which could cause investors to lose confidence in our financial statements or cause our stock price to decline. In future periods, we may identify additional deficiencies in our system of internal control over financial reporting during the course of our remediation efforts that may require additional work to address. Any future material weaknesses in internal control over financial reporting could result in material misstatements in our financial statements and we could be required to restate our financial results, which could lead to substantial additional costs for accounting and legal fees and shareholder litigation. Moreover, any future disclosures of additional weaknesses, or errors as a result of those weaknesses, could result in investors losing confidence in our reported financial information and may lead to a decline in the stock price. For more information about these material weaknesses, see Item 9A, "Controls and Procedures".

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews or becomes aware of either during the conduct of an audit, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In particular, Section 404 of the Sarbanes-Oxley Act will require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. Pursuant to Section 404, as of December 31, 2020, once we are no longer an "emerging growth company," and provided we also qualify as an "accelerated filer" or a "large accelerated filer," we will be required to provide an annual management report on the effectiveness of our internal control over financial reporting and we will also be required to include with such annual report an attestation report on internal controls over financial reporting issued by our independent registered public accounting firm. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that we have not maintained effective internal controls over financial reporting, in all material respects. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our common stock.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize PDS0101.

PDS0101 is still in early-stage clinical development and will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for any indication or for any other treatment regime. We cannot predict with any certainty if or when it might submit a BLA for regulatory approval for PDS0101 or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for PDS0101 will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In later stages of clinical trials, PDS0101 may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials of PDS0101 therefore may not be predictive of the results of our planned Phase 1 and 2 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their immunotherapies performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and different cancers than we have studied in Phase 1/2A clinical trials to date, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize PDS0101, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts with prospective trial sites, or they may be unwilling to conduct studies based on out protocols;
- clinical trials of PDS0101 may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of PDS0101 may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of PDS0101 may be greater than we anticipate; and
- the supply or quality of PDS0101 or other materials necessary to conduct clinical trials of PDS0101 may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of PDS0101 beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of PDS0101 or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for PDS0101;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize PDS0101, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize PDS0101, any of which may harm our business and results of operations.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of PDS0101 may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study.

Furthermore, any negative results we may report in clinical trials of PDS0101 may make it difficult or impossible to recruit and retain participants in other clinical trials of PDS0101. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop PDS0101, or could render further development impractical. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, PDS0101 could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with PDS0101 even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like Advaxis, Transgene, ISA Pharmaceuticals, Genexine, and Inovio as well as Etubics, Vaccibody, Admedus, Cel-Sci, Neo-ImmuneTech, Kite Pharma, Immune Design, Dynavax, Bavarian Nordic, Seattle Genetics, and Selecta Bioscience, each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and competes with others in acquiring technology from such universities and institutions.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than PDS0101.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other cancers and infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize immunotherapies that are superior to other alternatives in the market;
- demonstrate through our clinical trials that PDS0101 is differentiated from existing and future therapies;
- attract qualified scientific, immunotherapy development and commercial personnel;
- obtain additional patent or other proprietary protection for PDS0101;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new applications for PDS0101 or immunotherapies.

The availability of our competitors' immunotherapies and other treatments could limit the demand, and the price we are able to charge, for PDS0101. The inability to compete with existing or subsequently introduced immunotherapies and other treatments would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could PDS0101 less competitive. In addition, any new immunotherapy that competes with an approved treatment must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

PDS0101 may cause adverse effects or have other properties that could delay or prevent its regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by PDS0101 could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If clinical trials for PDS0101 report an unacceptable frequency or severity of adverse events, our ability to obtain regulatory approval for PDS0101 may be negatively impacted.

Furthermore, if PDS0101 is approved and then causes serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of PDS0101 or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way PDS0101 is administered or to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could elect to discontinue the sale of PDS0101; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of PDS0101 and could substantially increase the costs of commercialization.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, PDS0101, and our ability to generate revenue will be impaired.

PDS0101 and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for PDS0101 will prevent us from commercializing PDS0101. We have not received approval to market a PDS0101 from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the safety and efficacy of PDS0101. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. PDS0101 may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude it from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of PDS0101. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. There may be regulatory questions or disagreements regarding interpretations of data and results at any stage. For example FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks.

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, certain of our scientific advisors or consultants who receive compensation from us are clinical trial investigators for our clinical trial. Although we believe our existing relationships are within the FDA's guidelines, if these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing PDS0101 or any other product candidates.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize PDS0101 in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market PDS0101 in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions.

In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of PDS0101 in those countries. PDS0101 is not approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced.

Our product candidates are in various stages of development.

Favorable results in pre-clinical or early stage clinical trials may not be predictive of success in later clinical trials and may not lead to commercially viable products for any of several reasons. For example, our product candidates may fail to be safe and effective in clinical trials or additional pre-clinical studies, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. Our product candidates will require significant additional development, clinical trials, regulatory clearances and additional investment by us before they can be commercialized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and PDS0101 may face future development and regulatory difficulties.

Marketing of PDS0101, if approved, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for PDS0101, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current Good Clinical Practice, or cGCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of PDS0101 is granted, the approval may be subject to limitations on the indicated uses for which PDS0101 may be marketed or to the conditions of approval. If PDS0101 receives marketing approval, an accompanying label may limit the approved use of PDS0101, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of PDS0101. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we promote or otherwise market PDS0101 for indications other than those for which it is approved, we may be subject to certain enforcement actions. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription biopharmaceutical products may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with PDS0101, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing PDS0101;
- restrictions on the labeling or marketing of PDS0101;
- restrictions on PDS0101 distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of PDS0101 from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of PDS0101;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of PDS0101;
- seizures of PDS0101; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of PDS0101. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approvals or licenses that we may have obtained.

Even if PDS0101 receives licensure, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If PDS0101 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If PDS0101 does not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer PDS0101 for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers PDS0101 in addition to or in the place of other immunotherapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of PDS0101 together with other medications.

Because we expect sales of PDS0101, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of PDS0101 to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we otherwise plan.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are initially developing our lead product candidate, PDS0101 and the other Versamune ® Products. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we fail to comply with federal and state healthcare regulatory laws, including in our relationships with healthcare providers and customers and third-party payors, we could face criminal prosecution and sanctions, substantial civil penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, and the curtailment of our operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third-party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business, particularly if and when we commercialize any product candidates and if and when payment becomes available from payors for our products. The laws that may affect our ability to operate include, but are not limited to:

The Federal Anti-Kickback Statute (AKS), which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The Affordable Care Act, among other things, amended the intent requirements of the federal AKS. A person or entity can now be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the FCA.

The False Claims Act's civil provisions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. Intent to deceive is not required to establish liability under the civil False Claims Act.

The False Claims Act's criminal provisions, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, prohibits, among other actions, executing or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters.

HIPAA, as amended by the HITECH Act, and its respective implementing regulations, now makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.

Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 USC § 45(a), given that even for entities that are not deemed "covered entities" or "business associates" under HIPAA, according to the United States Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of its laws. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

The federal "Sunshine" and "Open Payments" requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively, the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures." In 2022 the Sunshine Act will be extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to healthcare providers.

state law equivalents of each of the above federal laws and state laws otherwise addressing the pharmaceutical and healthcare industries, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases that may apply regardless of payor, i.e., even if reimbursement is not available; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines (the PhRMA Code) and the relevant compliance program guidance promulgated by the federal government (HHS-OIG), or otherwise prohibit, restrict or impose tracking and disclosure requirements related to payments, gifts, or others remuneration that may be made to healthcare providers and other potential referral sources, or marketing practices to such persons and entities or drug pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018) and state laws governing the privacy and security of information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and may apply more broadly than HIPAA, thus complicating compliance efforts – for example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information.

In our business, healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of our product candidates, if approved for marketing. Moreover, while we do not plan to submit claims and our customers will make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. Current or future arrangements with physicians and other healthcare providers and customers, and third-party payors, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement or failed to comply with government price reporting requirements, or engaged in off-label promotion of products, we could face action by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and employment arrangements with individuals, physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who serve as clinical investigators in our clinical trials, or influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of PDS0101.

We face an inherent risk of product liability exposure related to the testing of PDS0101 in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for PDS0101 or other immunotherapies that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $5 million per claim and $5 million in the aggregate, it may not be adequate to cover all liabilities that it may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, it may not be successful in commercializing PDS0101, if approved.

We do not have any infrastructure for the sales, marketing or distribution of PDS0101, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market PDS0101, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for PDS0101, we will need either our own, or a third party's, sales and marketing organization. There are significant expenses and risks involved with creating teams for, or contracting for, sales, marketing and distribution capabilities. Any failure or delay in the development of our sales, marketing and distribution capabilities, either internally or in collaboration with third parties, could delay the launch of PDS0101, which would adversely affect commercialization.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize PDS0101 outside of the United States, a variety of risks associated with international operations could harm our business.

If PDS0101 is approved for commercialization, we may enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Recently enacted and future healthcare legislation, regulations, and policy initiatives may increase the difficulty and cost for us to obtain marketing approval of and commercialize PDS0101 and affect the prices we may obtain and our profitability.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of PDS0101, restrict or regulate post-approval activities and affect our ability to profitably sell PDS0101.

For example, in March 2010, Affordable Care Act was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although the full effect of the Affordable Care Act may not yet be fully understood, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

As another example, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription biopharmaceuticals in finished dosage forms for commercial distribution. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for immunotherapies, which could result in reduced demand for PDS0101 or additional pricing pressures.

Risks Related to Our Dependence on Third Parties

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

We currently have agreements with various third-party manufacturing facilities for production of PDS0101 for research and development and testing purposes. We depend on third-party manufacturers to supply our preclinical and clinical materials and will be reliant on a third-party manufacturer to produce PDS0101 on a commercial scale, should that product receive regulatory approval. Third-party manufacturers must be able to meet our deadlines and adhere to quality standards and specifications. Our predominant reliance on third parties for the manufacture of PDS0101 creates a dependency that could severely disrupt our research and development, clinical testing, and sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. There is no assurance that any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs ' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for PDS0101. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize PDS0101. As a result, our financial results and the commercial prospects for PDS0101 would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.

Our strategy may include potential reliance upon strategic collaborations for marketing and commercialization of PDS0101 and other Versamune ® Products. We also rely on strategic collaborations for research, development, marketing and commercialization for PDS0101 and other Versamune® Products. We have also been heavily reliant upon third party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for PDS0101 and other Versamune® Products, the costs and complexities of manufacturing and delivering PDS0101 and other Versamune® Products to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative immunotherapies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for PDS0101 and other Versamune® Products.

Our current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of PDS0101 and other Versamune ® Products or the generation of sales revenue. To the extent that we have entered or will enter into co-promotion or other collaborative arrangements, PDS0101 and other Versamune® Products revenues are likely to be lower than if we directly marketed and sold any products that we develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- financial funding to support said collaboration;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations, our success will in part depend on the performance of our collaborators. We will not directly control the amount or timing of resources devoted by our collaborators to activities related to PDS0101 and other Versamune® Products. Our collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of PDS0101 and other Versamune® Products. If any collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. If we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements. Additionally, our collaborators may seek to renegotiate agreements we has entered into, or may disagree with us about the terms and implementation of these agreements. If collaborators disagree with us about the terms or implementation of our agreements, we may face legal claims that may involve considerable expense and could negatively affect our financial results.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of PDS0101 and other Versamune ® Products, if approved for marketing. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring immunotherapy manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Our business could be adversely affected by the effects of health epidemics, pandemics, or outbreaks of infectious diseases, including the recent COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in New Jersey, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. For example, in December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of March 2020, has spread to over 100 countries, including the United States.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Similarly, the State of New Jersey declared a state of emergency related to the spread of COVID-19 , and many counties have announced aggressive recommendations to reduce the spread of the disease. Several state and local governmental agencies in the United States have also issued or publicly stated that they are considering issuing shelter-in-place orders, which generally (i) direct all individuals living in those locations to shelter at their places of residence (subject to limited exceptions), (ii) direct all businesses and governmental agencies to cease non-essential operations at physical locations in those locations, (iii) prohibit all non-essential gatherings of any number of individuals, and (iv) order cessation of all non-essential travel. While none of the counties within New Jersey are currently subject to such an order, one or more of those counties, including Mercer County, where our principal headquarters are located, may do so in the near future. In addition, we have implemented work-from-home policies for certain employees. The effects of any potential shelter-in-place orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. Further, on March 10, 2020, the FDA announced that it is postponing most foreign inspections through April 2020, effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis. This action may impact other FDA responsibilities, including product candidate application reviews. The FDA has indicated that it will utilize interim measures such as reviewing a firm's previous compliance history, using information shared from foreign governments as part of mutual recognition and confidentiality agreements and requesting records "in advance of or in lieu of" on-site drug inspections. Nevertheless, we cannot predict at this time whether this or other developments will cause delays or cause other situations that may impact our business. In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

The spread of COVID-19 , which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our Versamune® platform, PDS0101, or other Versamune® Products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Versamune ®. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to PDS0101. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-licenses may fail to result in issued patents with claims that cover PDS0101 or its applications in the United States or in other countries. There is no assurance that all potentially relevant prior art relating, which can invalidate a patent or prevent a patent from issuing from a pending patent application is known to us. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of PDS0101 and other Versamune® Products that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could exclusively market PDS0101 and other Versamune® Products under patent protection could be reduced.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect PDS0101 or other Versamune® Products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and immunotherapies. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent Office, or become involved in derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging its patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or immunotherapies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize PDS0101 without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize PDS0101 and other Versamune® Products.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and immunotherapies, or limit the duration of the patent protection of our technology and immunotherapies. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for PDS0101 and other Versamune® Products, we may be open to competition from generic versions of PDS0101 or other similar products using our technology. Given the amount of time required for the development, testing and regulatory review of new immunotherapy candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing immunotherapies similar or identical to ours.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in 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 patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on PDS0101 and other Versamune® Products. Such a loss of patent protection could harm our business.

We may also face claims that our products infringe patents that our competitors hold. Claims for alleged infringement and any resulting lawsuit, if successful, could subject us to significant liability for damages and invalidations of our proprietary rights. Any such lawsuit, regardless of our success, would likely be time consuming and expensive to resolve and would divert management time and attention. Any potential intellectual property litigation could also force us to do one or more of the following: (a) stop selling our products; (b) obtain a license(s), from the owner of any asserted intellectual property, to sell or use the relevant technology, which license may not be available on reasonable terms, or at all; or (c) redesign our products to avoid using the relevant technology.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also 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 an adverse effect on the price of our common stock.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect the Versamune ® platform, PDS0101 and other Versamune® Products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that it has licensed or that it might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering PDS0101 throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own immunotherapies and, further, may export otherwise infringing immunotherapies to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These immunotherapies may compete with PDS0101 in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

General Market Risk Factors

Our stock price is expected to be volatile, and the market price of our common stock may drop in the future.

The market price of our common stock may be subject to significant fluctuations in the future. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the ability of us and our partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of us or our partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure by us to maintain our existing third-party license, manufacturing and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about us, or if they issue an adverse or misleading opinions regarding our business and stock;
- if large short positions are taken in our stock and or negative reports are provided, whether they are based in fact or otherwise;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation.

We are required to meet the Nasdaq Capital Market's continued listing requirements and other Nasdaq rules, and if we fail to meet such rules and requirements, we may be subject to delisting. Delisting could negatively affect the price of our common stock, which could make it more difficult for us to sell securities in a future financing or for you to sell our common stock.

We are required to meet the continued listing requirements of the Nasdaq Capital Market and other Nasdaq rules, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price and certain other corporate governance requirements. In particular, we are required to maintain a minimum bid price for our listed common stock of $1.00 per share. If we do not meet these continued listing requirements, our common stock could be delisted. Delisting from the Nasdaq Capital Market would cause us to pursue eligibility for trading of these securities on other markets or exchanges, including the OTC BB or QB markets, or on the OTC "pink sheets." In such case, our stockholders' ability to trade, or obtain quotations of the market value of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of our securities. There can be no assurance that our securities, if delisted from the Nasdaq Capital Market in the future, would be listed on a national securities exchange, a national quotation service, the OTC markets or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, cause us to lose eligibility to register the sale or resale of our shares on Form S-3 and the automatic exemption from registration under state securities laws for exchange-listed securities, adversely affect the market liquidity of our securities, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

We do not anticipate will pay any cash dividends in the foreseeable future.

We currently expect to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our company will be the sole source of our stockholders' gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after certain legal restrictions on resale lapse, the trading price of our common stock could decline. As of December 31, 2019, we had 5,281,237 shares of common stock outstanding. Approximately 3,460,000 of such shares are freely tradable, without restriction, in the public market. Approximately 1,817,000 of such shares of common stock are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

Ownership of our common stock is highly concentrated, which may prevent our stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Our executive officers and directors and their affiliates beneficially own or control approximately 22% of the outstanding shares of our common stock as of December 31, 2019. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Because the Merger resulted in an ownership change under Section 382 of the Code for Edge, pre-merger U.S. net operating loss carryforwards and certain other tax attributes will be subject to limitations.

As of December 31, 2018, prior to completion of the Merger, Edge had federal and state net operating loss carryforwards, or NOLs, of $128.6 million and $27.1 million, respectively, due to prior period losses. If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's U.S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state and foreign tax laws. We believe that Edge may have already undergone one or more ownership changes prior to the Merger. However, the Merger also resulted in an ownership change for Edge and, accordingly, Edge's U.S. net operating loss carryforwards and certain other tax attributes available to us are subject to limitations on their use.

Changes in tax laws and regulations or our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.

Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate, which could adversely affect our business, financial condition, and operating results.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The changes included in the Tax Act are broad and complex. The impact of these changes on how the combined company's earnings are taxed include, among other items, (i) reducing the U.S. federal corporate tax rate from 35% to 21%; (ii) repealing the corporate alternative minimum tax and changing how existing credits can be utilized; (iii) temporarily providing for elective immediate expensing for certain depreciable property; (iv) creating a new limitation on the deductibility of interest expense; and (v) changing rules related to uses and limitations of net operating losses created in tax years beginning after December 31, 2017. We are continuing to evaluate the Tax Act and its impact on our business. It is possible that the Tax Act will be subject to further changes either in a technical corrections bill or entirely new legislation. The overall impact of the Tax Act also depends on the future interpretations and regulations that may be issued by U.S. tax authorities. We expect there will be further guidance provided by these authorities potentially having a material adverse effect on our financial condition or results of operations. The impact of broad proposals or of regulatory issuances on our business can vary substantially depending upon the specific changes or further guidance made and how the changes or guidance are implemented by the authorities.

Anti-takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our current or future management.

Because we are incorporated in Delaware, our company is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our eighth amended and restated certificate of incorporation, as amended, provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our eighth amended and restated certificate of incorporation, as amended, provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum, to the fullest extent permitted by law, for: (a) any derivative action or proceeding brought on our behalf; (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (c) any action asserting a claim arising pursuant to the DGCL, our eighth amended and restated certificate of incorporation, as amended, or our second amended and restated bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its' choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

If a court were to find the choice of forum provision contained in our eighth amended and restated certificate of incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

We qualify as an emerging growth company, and any decision on our part to comply with reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," and, we currently intend to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We cannot predict whether investors will find our common stock less attractive if we choose to rely on these exemptions while we are an emerging growth company. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We cannot predict whether investors will find our common stock less attractive if we choose to rely on these exemptions while we are an emerging growth company. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

As of December 31, 2020, we will no longer be an "emerging growth company". As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. The cost of compliance with Section 404 requires us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting as material weaknesses, we may be required to make prospective or retroactive changes to our financial statements, consider other areas for further attention or improvement, or be unable to obtain the required attestation in a timely manner, if at all. In addition, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Evaluation of Strategic Alternatives

Stockholder litigation and regulatory inquiries and investigations are expensive and could harm our business, financial condition and operating results and could divert management attention.

In the past, securities class action and/or stockholder derivative litigation and inquiries or investigations by regulatory authorities have often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from one or more clinical trials. In the future we may be the target of this type of action as a result of changes in our stock price, past transactions, results of clinical trials or other matters. Any stockholder litigation and/or regulatory investigations against us, whether or not resolved in our favor, could result in substantial costs and divert our management's attention from other business concerns, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

On July 8, 2019, we entered into a lease termination agreement for our office space located at 300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922 effective August 31, 2019. We maintain a month-to-month lease for our research facilities at the Princeton Innovation Center BioLabs located at 303A College Road E, Princeton, NJ 08540. We entered into a temporary month-to-month lease as of September 1, 2019 for office space located at 830 Morris Turnpike, Short Hills, NJ 07078.

On March 10, 2020, we entered into a sublease agreement, effective as of March 5, 2020, to occupy the office space located at 25B Vreeland Road, Suite 300, Florham Park, NJ. The sublease commences on May 1, 2020 and continues for a term of approximately forty (40) months with an option to renew through October 31, 2027. On March 17, 2020, the master lessor provided its consent to the sublease in accordance with the terms of the sublease.

ITEM 3. Legal Proceedings

From time to time in the ordinary course of our business, we are subject to claims, legal proceedings and disputes.

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

Our common stock is listed on the Nasdaq Capital Market under the symbol "PDSB". Prior to the Merger, our common stock was trading under the symbol "EDGE".

Stockholders

As of March 9, 2020, there were 52 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

Equity Compensation Plans

See "Part III, Item 11. Equity Compensation."

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Annual Report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report.

We are a clinical-stage biopharmaceutical company developing cancer immunotherapies that are designed to stimulate an antigen specific killer T-Cell response in a quantity and quality that significantly surpasses current approaches. PDS owns the Versamune®, T-cell activating platform, a proprietary multi-functional immunotherapy technology, which has been developed to encompass the attributes of the most successful immunotherapy approaches, such as checkpoint inhibitors, CAR-T cells and live-vector based vaccines, etc., while also overcoming their shortcomings.

It is well documented that the most critical attribute of an effective cancer immunotherapy is the induction of high levels of active antigen-specific CD8+ (killer) T-cells. Priming adequate levels of active CD8+ T-cells in-vivo continues to be a major obstacle facing immunotherapy. PDS0101 in its first human clinical trial confirmed the impressive preclinical study results and demonstrated the unique in-vivo induction of high levels of active HPV-specific CD8+ T-cells in humans.

We believe that the Versamune® platform has the potential to rapidly become an industry-leading immuno-oncology technology and is currently being applied to the development of a robust pipeline of valuable "new-generation, multi-functional" immunotherapies, both as single agents and as part of combination therapies with other leading immuno-oncology technologies. We expect substantial value accretion as its development-stage products successfully progress through upcoming human Phase 2 clinical trials.

The unique combination of high potency and excellent safety of the Versamune® platform observed in preclinical studies appears to be corroborated in a successfully completed 12-patient Phase 1 clinical trial. The Phase 1 human trial immune responses mirrored the strong reported T-cell responses seen in preclinical studies, which led to superior anti-tumor regression efficacy in pre-clinical head-to-head studies with leading clinical development-stage technologies. Superior anti-tumor response of PDS0101 monotherapy versus combinations of top competitors e.g. cancer vaccines + checkpoint inhibitors or chemotherapy was also demonstrated in preclinical studies. In a retrospective analysis not contemplated in the initial study design, it was observed that 6 out of 10 evaluable patients experienced complete regression of their pre-cancerous lesions despite the fact that the HPV16 specific therapy was used on patients who were co-infected with multiple strains of the HPV virus.

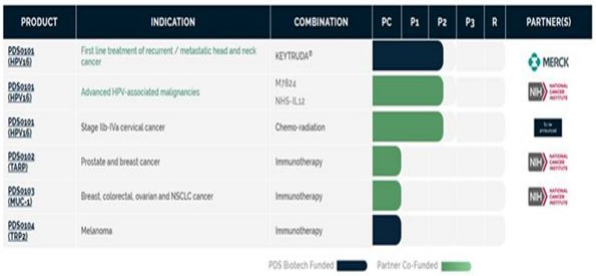
We believe that the rational design of combination immunotherapies using agents that promote synergy with each other and reduced potential for compounded toxicity would substantially improve potential for combination therapies to deliver improved clinical benefit for cancer patients. Versamune® appears to activate the appropriate combination of immunological pathways that promote strong CD8+ T-cell induction, while also altering the tumor's microenvironment to make the tumor more susceptible to T-cell attack, which PDS believes makes it an ideal complement to the checkpoint inhibitors by enhancing their potency. In addition, the differences in mechanism of action between Versamune® and checkpoint inhibitors, as well as the initial demonstrated safety profile of Versamune®, suggests that these combinations may be much better tolerated by patients than many or most other combination therapies involving checkpoint inhibitors.

On October 28, 2019, we entered into an amendment to the clinical trial collaboration agreement with a subsidiary of Merck (known as MSD International outside the United States and Canada) to evaluate the combination of PDS's lead Versamune®-based immunotherapy, PDS0101, with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase II clinical trial. The planned clinical trial will now evaluate the efficacy and safety of the combination as a first-line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection and is expected to be initiated in the first half of 2020. The modification to the clinical trial design to evaluate PDS0101 in combination with KEYTRUDA® as first-line treatment comes as a result of Merck's recent approval by the FDA on June 10, 2019 for first line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) using KEYTRUDA® in combination with platinum and fluorouracil (FU) for all patients and as a single agent for patients whose tumors express PD-L1 as determined by an FDA-approved test.

We previously announced that we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) for the development of the PDS0101 HPV cancer immunotherapy in combination with other immune-modulating agents as a potential treatment for advanced HPV-related cancers. Under the agreement, we will collaborate with the NCI's Genitourinary Malignancies Branch (GMB) and Laboratory of Tumor Immunology and Biology (LTIB) with plans to conduct a Phase 2 clinical study evaluating PDS0101 with novel immune-modulating agents M7824 and NHS-IL12 being studied at NCI as part of a CRADA with another EMD Serono (Merck KGaA). The phase 2 clinical study is anticipated to start in the first half of 2020. The CRADA also involves preclinical evaluation of PDS0101 in combination with other therapeutic modalities upon the mutual agreement of both parties.

Since our inception in 2005, we have devoted substantially all of our resources to developing our Versamune® platform, advancing preclinical programs, conducting clinical trials, manufacturing PDS0101 for clinical trials, and providing general and administrative support. We have funded our operations primarily from the issuance of common stock. We have not generated any product revenue.

Our current pipeline for PDS0101 is summarized in the table below. All trials are expected to be initiated in the first half of 2020. PDS is also developing a robust pipeline of product candidates. These candidates are also summarized below.



In June of 2019 the Versamune mechanism of action was published in one of the top peer reviewed journals in the field of immunology, (*Journal of immunology*, 2019(202), 1215).

During the third quarter of 2019, PDS received IRB approval to perform a retrospective analysis of the clinical benefit achieved by the patients who participate in the phase 1 clinical trial. Despite most of the patients being infected with multiple HPV strains other than HPV 16, complete regression of pre-cancerous lesions was documented in 6 out of 10 patients- strongly suggesting that the T-cells induced by PDS0101 were clinically active. As a result of this information strongly suggests the unique ability of PDS0101 to generate potent and biologically active CD8+ T-cells in-vivo, PDS altered its clinical strategy to focus on areas of more severe unmet medical need in which PDS0101 is combined with checkpoint inhibitors and standard of care to provide improved clinical benefit to patients. PDS feels that due to the ability of PDS0101 to generate potent HPV specific killer T-cell response, that the quickest path to demonstrating proof of concept in a larger trial with the least risk would be to perform these studies in combination with synergistic agents in indications where a more effective therapy is needed.

We believe that rational design of combination immunotherapies using agents that promote synergy with each other and reduced potential for compounded toxicity would substantially improve potential for combination therapies to deliver improved clinical benefit for cancer patients. Versamune® appears to activate the appropriate combination of immunological pathways that promote strong CD8+ T-cell induction, while also altering the tumor's microenvironment to make the tumor more susceptible to T-cell attack, which PDS believes makes it an ideal complement to the checkpoint inhibitors by enhancing their potency. In addition, the differences in mechanism of action between Versamune® and checkpoint inhibitors, as well as the initial demonstrated safety profile of Versamune®, suggests that these combinations may be much better tolerated by patients than many or most other combination therapies involving checkpoint inhibitors.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $7.0 million, and $3.8 million for the years ended December 31, 2019 and 2018 respectively. As of December 31, 2019, we had an accumulated deficit of $28.9 million. Substantially all of our net losses have resulted from costs incurred in connection with its research and development programs and from general and administrative costs associated with these operations.

As of December 31, 2019, we had $12.2 million in cash and cash equivalents.

Our future funding requirements will depend on many factors, including the following:

- the timing and costs of our planned clinical trials;
- the timing and costs of our planned preclinical studies of its Versamune® platform;
- the outcome, timing and costs of seeking regulatory approvals;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
- the extent to which we in-licenses or acquires other products and technologies.

Corporate Information

We currently operate the existing business of Private PDS (as defined below) as a publicly traded company under the name PDS Biotechnology Corporation. We were incorporated as Edge Therapeutics, Inc., or Edge, on January 22, 2009. Upon closing of the Merger (as defined below), we suspended Edge's prior business and prioritized the business of PDS Biotechnology Corporation, a privately held Delaware corporation, which we refer to as Private PDS, which is a clinical-stage biopharmaceutical company developing multi-dimensional cancer immunotherapies that are designed to overcome the limitations of the current approaches.

On March 15, 2019, we completed our previously disclosed reverse merger with Private PDS, which we refer to as the Merger, pursuant to and in accordance with the terms of the Agreement and Plan of Merger, dated as of November 23, 2018, as amended on January 24, 2019, by and among Edge, Echos Merger Sub, a wholly-owned subsidiary of Edge, which we refer to as Merger Sub, and Private PDS, whereby Private PDS merged with and into Merger Sub, with Private PDS surviving as our wholly-owned subsidiary. In connection with and immediately following completion of the Merger, we effected a 1-for-20 reverse stock split, or the Reverse Stock Split, and changed our corporate name from Edge Therapeutics, Inc. to PDS Biotechnology Corporation, and Private PDS changed its name to PDS Operating Corporation. All of the outstanding stock of Private PDS was converted into shares of our common stock or canceled upon closing of the Merger.

Following the Merger, the stockholders of Private PDS effectively control the combined company, and, accordingly, Private PDS is deemed to be the accounting acquirer in the Merger. Accordingly, upon consummation of the Merger, the historical financial statements of Private PDS became our historical financial statements, and the historical financial statements of Private PDS are included in the comparative prior periods below. See "Note 1 – Nature of Operations" and "Note 4 – Reverse Merger" in our financial statements in Part I for more information on the Merger.

Financial Operations Overview

Revenue

We have not generated any revenues from commercial product sales and do not expect to generate any such revenue in the near future. We may generate revenue in the future from a combination of research and development payments, license fees and other upfront payments or milestone payments.

Research and Development Expenses

Research and development expenses include employee-related expenses, licensing fees to use certain technology in our research and development projects, costs of acquiring, developing and manufacturing clinical trial materials, as well as fees paid to consultants and various entities that perform certain research and testing on our behalf. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed consolidated financial statements as prepaid or accrued expenses. Costs incurred in connection with research and development activities are expensed as incurred.

As a result of the Merger, we acquired an in process research and development asset (IPR&D) for $2,974 relating to Edge's NEWTON 2 trials that we initially sought to find partners interested in continuing the development of these product candidates. Following the discontinuation of the NEWTON 2 trial for EG-1962, Edge had ceased all research and development efforts related to EG-1962 and suspended efforts on other legacy Edge product candidates. As of December 31, 2019, based on the limited prospects for partners we are no longer actively seeking partners to continue the development of these product candidates and pursue them to commercialization. Accordingly, we recorded an impairment charge IPR&D of $2,974 for the estimated value of the IPR&D asset of IPR&D asset of $2,974 in our consolidated statements of operations and comprehensive loss.

We expect that our research and development expenses will increase significantly over the next several years as we advance our Versamune®-based immuno-oncology, or I-O, candidates into and through clinical trials, pursues regulatory approval of our injectable Versamune® candidates and prepare for a possible commercial launch, all of which will also require a significant investment in contract and internal manufacturing and inventory related costs.

The process of conducting human clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our injectable I-O candidates. The probability of successful commercialization of our I-O candidates may be affected by numerous factors, including clinical data obtained in future trials, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

The following table summarizes our research and development expenses incurred for the periods indicated (in thousands):

	Year Ended December 31,	
	2019	2018
PDS0101 project	$ 3,194	$ 157
Clinical consulting	399	337
Regulatory consulting	287	-
Salaries and other costs	2,220	337
Total	$ 6,100	$ 831

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, business development and support functions. Other general and administrative expenses include travel expenses, professional fees for auditing, tax and legal services and facility-related costs.

Lease Termination and Disposal Costs

The lease termination costs relate to moving our corporate offices and consists of $0.7 million for lease termination fees and $0.3 million for disposal of leasehold improvements and office furniture.

Other Income

Other income consists of interest income consists of interest income earned on our cash and cash equivalents and interest expense.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP.

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses at the date of the consolidated financial statements and during the reporting periods, and to disclose contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates. The most significant estimates relate to the recognition and measurement of assets acquired and liabilities assumed in the acquisition, assessment of indicators of impairment for our intangible assets and the fair value of securities underlying stock-based compensation and other equity awards.

While our significant accounting policies are described in the notes to our financial statements appearing in this Annual Report, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Acquisition

Our consolidated financial statements include the operations of an acquired business after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of IPR&D be recorded on the balance sheet. Transaction costs are expensed as incurred.

Amounts recorded in connection with an acquisition can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions.

We are required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value in the initial recognition of net assets acquired in a business combination and when measuring impairment losses. We estimate fair value using an exit price approach, which requires, among other things, that we determine the price that would be received to sell an asset or paid to transfer a liability in an orderly market. The determination of an exit price is considered from the perspective of market participants, considering the highest and best use of non-financial assets and, for liabilities, assuming that the risk of non-performance will be the same before and after the transfer.

When estimating fair value, depending on the nature and complexity of the asset or liability, we may use one or all of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.
- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.
- Cost approach, which is based on the cost to acquire or construct comparable assets, less an allowance for functional and/or economic obsolescence.

Our fair value methodologies depend on the following types of inputs:

- Quoted prices for identical assets or liabilities in active markets (Level 1 inputs).
- Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means (Level 2 inputs).
- Unobservable inputs that reflect estimates and assumptions (Level 3 inputs).

A single estimate of fair value can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions.

On March 15, 2019, as a result of our merger with Edge Therapeutics, Inc., we recognized an IPR&D asset estimated to be $2,974,000 using the discounted cash flow method based on probability- adjusted cash flow success scenarios to develop EG-1962 into a commercial product, estimating the revenue and costs. We started with a forecast of all the expected net cash flows associated with the asset, which includes the application of a terminal value for indefinite-lived assets, and then we applied an asset-specific discount rate to arrive at a net present value amount. Some of the more significant estimates and assumptions inherent in this approach included: the amount and timing of the projected net cash flows, which includes the expected impact of competitive, legal and/or regulatory forces on the projections and the impact of technological risk associated with IPR&D assets, as well as the selection of a long-term growth rate; the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and the tax rate.

Asset Impairment

We review all of our long-lived assets for impairment indicators throughout the year. We perform impairment testing for indefinite-lived intangible assets annually and for all other long-lived assets whenever impairment indicators are present. When necessary, we record charges for impairments of long-lived assets for the amount by which the fair value is less than the carrying value of these assets.

Income Taxes

We file U.S. federal income tax returns and New Jersey state tax returns. Our deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards and are recorded using enacted tax rates expected to be in effect in the years in which these temporary differences are expected to be utilized. At December 31, 2019, we had federal net operating loss, or NOL, carryforwards of approximately $79.1 million, $13.6 million of which expire at various dates between 2029 and 2038, losses generated in 2018 or later of $6.5 million will carry forward indefinitely. At December 31, 2019, we had federal research and development credits carryforwards of approximately $0.7 million. We may be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon our value immediately before the ownership change, changes to our capital during a specified period prior to the change, and the federal published interest rate. Although we have not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

Accrued Clinical Expenses

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones.

When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred.

Stock-based Compensation

We estimate the fair value of our stock-based option awards to employees, directors and non-employees using the Black-Scholes option-pricing model, which requires the following assumptions: (1) the expected volatility of our stock is based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available, (2) the expected term of the award is based on the simplified method, which is the midpoint between the requisite service period and the contractual term of the option, as we have a limited history of being a public company from March 15, 2019 (the date of the Merger) to develop reasonable expectations about future exercise patterns and employment duration for our options, (3) the risk-free interest rate based on U.S. Treasury notes with a term approximating the expected life of the option and (4) expected dividend yield of 0, since we have never paid cash dividends and have no present intention to pay cash dividends.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

	Year Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 6,100	$ 831	$ 5,269	634%
General and administrative expenses	10,982	2,788	8,194	294%
Impairment expenses IPRD	2,974	–	2,974	100%
Lease termination and disposal costs	979	–	979	100%
Depreciation and amortization	–	27	(27)	100%
Total operating expenses	21,035	3,646	17,389	477%
Loss from operations	(21,035)	(3,646)	(17,389)	100%
Bargain purchase gain	13,335	–	13,335	100%
Loss on extinguisment of debt	–	(185)	185	100%
Interest (expense), net	320	(5)	325	100%
Loss before income taxes	(7,380)	(3,836)	(3,544)	100%
Income taxes (benefit)	(382)	–	(382)	92%
Net loss and comprehensive loss	$ (6,998)	$ (3,836)	$ (3,162)	82%

Research and Development Expenses

Research and development (R&D) expenses increased to $6.1 million for the year ended December 31, 2019 from $0.8 million for the same period in 2018. The increase of $5.3 million was primarily attributable to an increase in external expenses for clinical studies of $2.9 million and internal R&D personnel costs of $1.3 million, non-cash stock based compensation of $0.5 million and other departmental costs of $0.6 million.

General and Administrative Expenses

General and administrative expenses increased to $ 11.0 million for the year ended December 31, 2019 from $2.8 million for the same period in 2018. The $8.2 million increase was due to increases in personnel costs of $1.8 million, non-cash stock based compensation of $2.3 million, facilities costs of $0.7 million, D&O insurance costs of $1.2 million, legal fees of $1.5 million, professional fees of $0.4 million and $0.3 million in other operating expenses.

Impairment Charge - IPRD

Impairment charge-IPRD is attributable to the write-off of the intangible asset acquired as part of the merger.

Lease Termination and Disposal Costs

The lease termination costs relates to moving the Company's corporate offices and consists of $0.7 million for lease termination fees and $0.3 million for disposal of office furniture.

Bargain Purchase Gain

The bargain purchase gain of $13.3 million for the year ended December 31, 2019, is as a result of the Merger, representing the excess of the fair value of net assets acquired over the fair value of the common stock issued to acquire Private PDS in the Merger.

Loss on Extinguishment of debt

In 2018, the loss on extinguishment of debt of $185,800 was related to settlement agreement with one of our vendors.

Interest income (expense), net

Interest income (expense), net was $0.3 million during the year ended December 31, 2019, an increase of $0.3 million during the year ended December 31, 2018, due primarily to interest received on invested cash and cash equivalents.

Liquidity and Capital Resources

As of December 31, 2019, we had $12.2 million of cash and cash equivalents, primarily derived from the $29.1 million of pre-existing cash on Edge's balance sheets that we obtained as a result of the Merger.

In February 2020, we completed an underwritten public offering, in which we sold 10,000,000 shares of common stock at a public offering price of $1.30 per share. The shares sold included 769,230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price. We received gross proceeds of approximately $13 million and net proceeds of approximately $11.9 million after deducting underwriting discounts and commissions.

Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Annual Report on Form 10-K. Our budgeted cash requirements in 2020 and beyond include expenses related to continuing development and clinical studies. Based on our available cash resources and cash flow projections as of the date the consolidated financial statements were available for issuance, which includes additional proceeds of $11.9 million from our February 2020 offering, we believe there are sufficient funds to continue operations and research and development programs for at least 12 months from the date of this report. Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources. These financial resources may not be adequate to sustain our operations.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financings. However, the Company cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its existing stockholders. We may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market immunotherapies that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects. Failure to obtain adequate financing also may adversely affect its ability to operate as a going concern.

On July 29, 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, pursuant to which, we have the right, in our sole discretion, to present Aspire Capital Fund, LLC, or Aspire Capital, with a purchase notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, in an aggregate amount of up to $20.0 million of our common stock, or the Purchased Shares, over the term of the Aspire Purchase Agreement at a per share price equal to the lesser of the lowest sale price of our common stock on the purchase date or the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date. We may sell an aggregate of 1,034,979 shares of our common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. We may sell additional shares of our common stock above the 19.99% limit provided that (i) we obtain stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of our common stock on July 26, 2019. The minimum price at which we can sell shares under the Aspire Purchase Agreement is $0.50. On July 29, 2019, we issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. We recorded the fair value of the shares at July 29, 2019 of $603,924 as an expense in the third quarter of 2019. Concurrently with the Aspire Purchase Agreement, we entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement. In accordance with the Registration Rights Agreement, on August 20, 2019 we filed a Registration Statement on Form S-1 (File No. 333-232988) to cover the resale of the Commitment Shares and any Purchased Shares issuable to Aspire Capital under the Aspire Purchase Agreement. There is market uncertainty regarding the utilization of financing associated from the Aspire Purchase Agreement. As of December 31, 2019, no Purchase Shares were sold to Aspire Capital under the Aspire Purchase Agreement.

In February 2020, we completed an underwritten public offering, in which we sold 10,000,000 shares of common stock at a public offering price of $1.30 per share. The shares sold included 769,230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price. We received gross proceeds of approximately $13 million and net proceeds of approximately $11.9 million after deducting underwriting discounts and commissions.

Cash flows

The following table shows a summary of our cash flows for each of the years indicated (in thousands):

	Year Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (18,073)	$ (1,569)
Net cash provided by investing activities	29,381	–
Net cash provided by financing activities	750	1,497
Net increase in cash	$ 12,058	$ (72)

Net Cash Used in Operating Activities

Net cash used in operating activities was $18.1 million and $1.6 million for the years ended December 31, 2019 and 2018, respectively. The increase in cash used in operating activities of $16.5 million was primarily due to the increase in research and development costs, increase in general and administrative expenses including payment of Merger related costs, and payments of liabilities that had built up prior to the Merger as compared to the prior year.

Net Cash Provided by Investing Activities

Net cash provided by investing activities in 2019 relates primarily to cash acquired in the Merger.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $0.8 million and $1.5 million for the year ended December 31, 2019 and 2018 was due primarily to the receipt of net proceeds from the issuance of common stock.

Operating Capital Requirements

To date, we have not generated any product revenue. We do not know when, or if, we will generate any product revenue and we do not expect to generate significant product revenue unless and until we obtain regulatory approval and commercialize one of our current or future tablet vaccine candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our tablet vaccine candidates, and begin to commercialize any approved vaccine candidates. We are subject to all of the risks incident in the development of new products, and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect to incur additional costs associated with operating as a public company and anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our available cash resources and cash flow projections as of the date the consolidated financial statements were available for issuance, which includes additional proceeds of $11.9 million from our February 2020 offering, we believe there are sufficient funds to continue operations and research and development programs for at least 12 months from the date of this report.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize our tablet vaccines on our own; and
- the initiation, progress, timing and results of our commercialization of our tablet vaccine candidates, if approved, for commercial sale.

Please see the section titled “Risk Factors” elsewhere in this Annual Report for additional risks associated with our operations.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations as of the date indicated:

As of December 31, 2019	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Milestone payments	$ 550	$ 110	$ 220	$ 220	$ –
Total contractual obligations	$ 550	$ 110	$ 220	$ 220	$ –

The table above does not include (a) any milestone payments related to contingent events which may become payable to third parties under our license agreements as the timing and likelihood of such payments are not known, or (b) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

Purchase Commitments

We have no material non-cancelable purchase commitments with service providers as we have generally contracted on a cancelable, purchase order basis.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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

Off-balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

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

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15 (e)) under the Exchange Act as of the end of the period covered by this report. Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures, as a result of the material weaknesses in the Company's internal control described below, were not effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a—15(f) and 15d-15(f) under the Exchange Act).Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. GAAP.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. A control system, no matter how well conceived, operated, tested and monitored, can provide only reasonable, not absolute, assurance that the objectives of the control system are met because of inherent limitations.

Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (the COSO 2013 Framework). As a result of management's evaluation of the effectiveness of the Company's internal control over financial reporting, management concluded that as of December 31, 2019, the company had material weaknesses relating to four components of the COSO framework. These material weaknesses are summarized below, and remediation efforts are outlined in the "Remediation Plan" section below.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act.

Material Weaknesses in Internal Control over Financial Reporting

As of December 31, 2019, we identified a material weakness in four components of internal control as defined by COSO 2013 (Control Environment, Risk Assessment, Control Activities and Information & Communication). These material weaknesses resulted in the immaterial error correction of the consolidated financial statements and related notes as of December 31, 2018 and for the year then ended and immaterial errors corrected within the consolidated financial statements as of and for the year then ended December 31, 2019. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis by the company's internal controls.

Control Environment - The Company did not have adequate finance and accounting personnel with the appropriate U.S. GAAP technical expertise to identify, evaluate and account for complex and non-routine transactions.

Risk Assessment – The Company did not maintain an effective risk assessment that successfully identified and assessed risks of misstatement to ensure controls were designed and implemented to respond to the risks related to the reverse-merger transaction.

Information & Communication – The Company did not maintain an effective information and communication process to identify, capture and process relevant financial information necessary for financial accounting and reporting.

As a consequence, the Company did not have effective control activities related to the design, implementation and operation for process level control activities related to equity transactions, stock-based compensation, recognition of intangible assets, debt extinguishment, and business combination transaction costs.

Due to the existence of the above material weaknesses, management, including the CEO and CFO, has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2019. These material weaknesses create a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis.

Remediation Plan

While the Company believes it has improved its organizational capabilities, the material weaknesses remained unremediated as of December 31, 2019 and the Company's remediation activities are continuing to take place in 2020. The Company continues to strengthen our internal control over financial reporting and are committed to ensuring that such controls are designed and operating effectively. We have taken or are in the process of taking the following actions to begin to address the material weaknesses described above:

- The Company has supplemented existing accounting resources with external advisors to assist with performing technical accounting activities;
- The Company plans to continue to hire employees, including a Chief Financial Officer, with technical accounting expertise and public company experience on an as needed basis to the extent the Company determines such employees are necessary to perform the Company's technical accounting activities;
- The Company is enhancing the review controls, including controls to identify, capture and process relevant financial information necessary over the application of U.S. GAAP and accounting measurements for significant accounts, transactions and related financial statement disclosures on a timely basis;
- The Company is developing and implementing a comprehensive and continuous risk assessment process to identify and assess risks of material misstatement and ensure that the impacted financial reporting processes and related internal controls are properly designed and in place to respond to those risks in our financial reporting.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of these measures is ongoing and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing management review. We will not be able to conclude whether the steps we are taking will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weaknesses expeditiously.

Changes in Internal Control over Financial Reporting

In addition to the Company's identification and assessment of the material weakness described above, we are currently integrating our pre-Merger business into the pre-established internal control framework of Edge Therapeutics through the acquisition, including internal controls and information systems. This work began upon completion of the Merger in March 2019 and will continue into calendar year 2020. Edge Therapeutics was previously subject to the provisions of the Sarbanes-Oxley Act of 2002, as amended, whereas PDS Biotechnology Corporation, which prior to the Merger was a private, non-reporting operating company was not. Our company has an appropriate structure for internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period March 15, 2019 to December 31, 2019.

ITEM 9B. Other Information

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file a definitive Proxy Statement for the Annual Meeting of Stockholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (the Proxy Statement), not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and the applicable information included in the Proxy Statement is incorporated herein by reference.

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference to the Proxy Statement.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets
Consolidated Statements of Operations and Comprehensive Loss
Consolidated Statements of Convertible Preferred Stock and Changes in Stockholders' Equity (Deficit)
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits filed as part of this Annual Report are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

ITEM 16. Form 10-K Summary

None.

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger and Reorganization, dated November 23, 2018, by and among Edge Therapeutics, Inc., Echos Merger Sub, Inc. and PDS Biotechnology Corporation (filed as exhibit 2.1 to the Company's Current Report on Form 8-K filed on November 26, 2018, and incorporated by reference herein).
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated January 24, 2019, by and among Edge Therapeutics, Inc., Echos Merger Sub, Inc. and PDS Biotechnology Corporation (filed as exhibit 2.1 to the Company's Current Report on Form 8-K filed on January 30, 2019, and incorporated by reference herein).
2.3	Form of Support Agreement by and among Edge Therapeutics, Inc., Echos Merger Sub, Inc., PDS Biotechnology Corporation and certain of PDS Biotechnology Corporation's directors, officers and stockholders (filed as exhibit 2.2 to the Company's Current Report on Form 8-K filed on November 26, 2018, and incorporated by reference herein).
2.4	Form of Support Agreement by and among Edge Therapeutics, Inc., Echos Merger Sub, Inc., PDS Biotechnology Corporation and certain of Edge Therapeutics, Inc.'s directors, officers and stockholders (filed as exhibit 2.3 to the Company's Current Report on Form 8-K filed on November 26, 2018, and incorporated by reference herein).
3.1	Eighth Amended and Restated Certificate of Incorporation of Edge Therapeutics, Inc. (filed as exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein).
3.2	Second Amended and Restated Bylaws of Edge Therapeutics, Inc. (filed as exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K on March 18, 2019, and incorporated by reference herein).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K on March 18, 2019, and incorporated by reference herein).
4.1	Form of Certificate of Common Stock. (filed as exhibit 4.1 to the Company's Pre-Effective Amendment No. 1 to the registration statement on Form S-1 (File No. 333- 206416) filed on September 21, 2015, and incorporated by reference herein).
4.2	Warrant to Purchase 16,667 Shares of Capital Stock Issued to New Jersey Economic Development Authority, dated as of May 3, 2010. (filed as exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-206416) filed on September 21, 2015, and incorporated by reference herein).
4.3	First Amendment to Warrant Issued to New Jersey Economic Development Authority, dated October 9, 2013 (filed as exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.4	Form of Warrant Issued to Series B-1 Stockholders. (filed as exhibit 4.4 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.5	Form of Warrant to Purchase Series C Preferred Stock issued to Maxim Group LLC. (filed as exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.6	Warrant Agreement, dated as of August 28, 2014, by and between the Company and Hercules. (filed as exhibit 4.6 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.7	Form of Warrant to Purchase Series C-1 Preferred Stock issued to Maxim Group LLC. (filed as exhibit 4.7 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.8	Investors' Rights Agreement, dated as of April 6, 2015, by and among the Company and the Investors named therein. (filed as exhibit 4.8 to the Company's Registration Statement on Form S-1 (File No. 333- 206416) filed on August 14, 2015, and incorporated by reference herein).
4.9	Warrant to Purchase 18,000 Shares of Common Stock issued to Maxim Partners LLC, dated as of October 6, 2015. (filed as exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed on November 6, 2015, and incorporated by reference herein).
4.10*	Description of Securities.

10.1+	Employment Agreement, dated October 11, 2018, by and between PDS Biotechnology Corporation and Frank K. Bedu-Addo (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-4 on December 21, 2018, and incorporated by reference herein).
10.2+	Consulting Services Agreement, dated December 15, 2014, by and between PDS Biotechnology Corporation and Gregory Freitag (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-4 on December 21, 2018, and incorporated by reference herein).
10.3+	Consulting Services Agreement, dated December 15, 2014, by and between PDS Biotechnology Corporation and DeLyle Bloomquist (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-4 on December 21, 2018, and incorporated by reference herein).
10.4+	Offer Letter, dated September 21, 2018, by and between PDS Biotechnology Corporation and Lauren Wood, MD. (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-4 on December 21, 2018, and incorporated by reference herein).
10.5+	Consulting Services Agreement, dated March 26, 2015, by and between PDS Biotechnology Corporation and Gregory Conn (filed as Exhibit 10.23 to the Company's Registration Statement on Form S-4 on December 21, 2018, and incorporated by reference herein).
10.6	Clinical Trial Collaboration and Supply Agreement, dated May 19, 2017, by and between PDS Biotechnology Corporation and MSD International GmbH (filed as Exhibit 10.24 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.7	Patent License Agreement, dated January 5, 2015, by and between PDS Biotechnology Corporation and National Institutes of Health, as amended by First Amendment, dated August 5, 2015 (filed as Exhibit 10.25 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.8	Cost Reimbursement Agreement, dated November 1, 2015, by and between PDS Biotechnology Corporation and University of Kentucky Research Foundation (filed as Exhibit 10.26 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.9	Cost Reimbursement Agreement, dated November 1, 2015, by and between PDS Biotechnology Corporation and University of Kentucky Research Foundation (filed as Exhibit 10.27 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.10	Public Health Service Cooperative Research & Development Agreement for Intramural-PHS Clinical Research, dated effective as of February 2, 2015, by and between the National Cancer Institute and PDS Biotechnology Corporation (filed as Exhibit 10.28 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.11	DOTAP Chloride Enantiomer License Agreement effective November 1, 2008, between Merck Eprova AG and PDS Biotechnology Corporation (filed as Exhibit 10.29 to the Company's Registration Statement on Form S-4/A on January 25, 2019, and incorporated by reference herein).
10.12+	Employment Agreement, effective June 1, 2019, by and between PDS Biotechnology Corporation and Gregory Conn (filed as Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q on August 1, 2019, and incorporated by reference herein).
10.13**	Licensing Agreement by and between Evonik Corporation (as successor in interest to SurModics Pharmaceuticals, Inc.) and Edge Therapeutics, Inc., dated as of October 20, 2010 (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 on August 14, 2015, and incorporated by reference herein).
10.14**	Amendment No. 1 to the License Agreement, effective as of September 21, 2015, by and between Edge Therapeutics, Inc. and Evonik Corporation (filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1/A on September 21, 2015, and incorporated by reference herein).
10.15**	Amended and Restated Master Formulation Development Agreement, by and between Edge Therapeutics, Inc. and Oakwood Laboratories LLC, dated as of June 30, 2017 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q on August 1, 2017, and incorporated by reference herein).
10.16**	Manufacturing and Supply Agreement, by and between Edge Therapeutics, Inc. and Oakwood Laboratories LLC., dated as of June 20, 2017 (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q on August 1, 2017, and incorporated by reference herein).

10.17+	PDS Biotechnology 2010 Equity Incentive Plan, and forms of agreement thereunder (filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1/A on September 21, 2015, and incorporated by reference herein).
10.18+	Amended and Restated PDS Biotechnology Corporation 2014 Equity Incentive Plan (filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.19+	Form of PDS Biotechnology Corporation Executive Stock Option Agreement (filed as Exhibit 99.2 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.20+	Form of PDS Biotechnology Corporation Employee Stock Option Agreement (filed as Exhibit 99.3 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.21+	PDS Biotechnology Corporation 2009 Stock Option Plan, as amended (filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.22+	PDS Biotechnology Corporation 2018 Stock Incentive Plan (filed as Exhibit 99.2 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.23+	Form of PDS Biotechnology Corporation Option Agreement for 2009 Stock Option Plan, as amended (filed as Exhibit 99.3 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.24+	Form of PDS Biotechnology Corporation Option Agreement for 2018 Stock Incentive Plan (filed as Exhibit 99.4 to the Company's Registration Statement on Form S-8 on June 4, 2019, and incorporated by reference herein).
10.25+	PDS Biotechnology Corporation 2019 Inducement Plan (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K on June 20, 2019, and incorporated by reference herein).
10.26+	Form of Stock Option Grant Notice and Stock Option Agreement under the 2019 Inducement Plan (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K on June 20, 2019, and incorporated by reference herein).
10.27+	Second Amended and Restated Executive Employment Agreement by and between Brian A. Leuthner and Edge Therapeutics, Inc., dated as of June 10, 2015 (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 on August 14, 2015, and incorporated by reference herein).
10.28+	Amended and Restated Executive Employment Agreement by and between Herbert J. Faleck and Edge Therapeutics, Inc., dated as of August 11, 2015 (filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 on August 14, 2015, and incorporated by reference herein).
10.29+	Executive Employment Agreement by and between W. Bradford Middlekauff and Edge Therapeutics, Inc., dated as of October 30, 2015 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K on November 5, 2015, and incorporated by reference herein).
10.30+	Employment Agreement by and between Alyssa Wyant and Edge Therapeutics, Inc., dated as of February 21, 2017 (filed as Exhibit 10.15 to the Company's Annual Report on Form 10-K on March 2, 2017, and incorporated by reference herein).
10.31+	Executive Employment Agreement by and between Andrew Saik and Edge Therapeutics, Inc., dated as of October 31, 2017 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K on November 1, 2017, and incorporated by reference herein).
10.32+	Form of Indemnification Agreement for officers and directors (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 on August 14, 2015, and incorporated by reference herein).
10.33	Lease dated February 8, 2016, between The Connell Company and Edge Therapeutics, Inc. (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q on May 3, 2016, and incorporated by reference herein).
10.34+	Offer Letter, dated February 1, 2019, by and between PDS Biotechnology Corporation and Lauren Wood, MD. (filed as Exhibit 10.13 to the Company's Quarterly Report on Form 10-Q on August 1, 2019, and incorporated by reference herein).
10.35	Common Stock Purchase Agreement, dated July 29, 2019, by and among the Company and Aspire Capital Fund, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K on July 30, 2019, and incorporated by reference herein).
10.36	Letter Agreement, dated February 3, 2019, by and among Edge Therapeutics, Inc., PDS Biotechnology Corporation and Brian A. Leuthner (filed as exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 4, 2019, and incorporated by reference herein).
10.37*	Sublease Agreement, effective as of March 5, 2020, by and between PDS Biotechnology Corporation and COWI North America, Inc.
23.1*	Consent of KPMG LLP.

23.2*	Consent of Haynie & Co.
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 (1)	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2 (1)	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

+ Indicates management contract or compensatory plan.

* Filed Herewith.

** Confidential Treatment has been requested with respect to certain portions of this Exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

PDS Biotechnology Corporation

March 27, 2020 By: /s/ Frank Bedu-Addu
Frank Bedu-Addu, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

March 27, 2020 By: /s/ Janetta Trochimiuk
Janetta Trochimiuk
Controller
(Principal Accounting Officer)

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

Signature	Title	Date
/s/ Frank Bedu-Addu Frank Bedu-Addu	President and Chief Executive Officer and Director *(Principal Executive Officer and Principal Financial Officer)*	March 27, 2020
/s/ Janetta Trochimiuk Janetta Trochimiuk	Controller *(Principal Accounting Officer)*	March 27, 2020
/s/ De Lyle W. Bloomquist De Lyle W. Bloomquist,	Director	March 27, 2020
/s/ Gregory Freitag Gregory Freitag J.D., CPA	Director	March 27, 2020
/s/ Stephen Glover Stephen Glover	Director	March 27, 2020
/s/ Sir Richard Sykes Sir Richard Sykes	Director	March 27, 2020
/s/ Kamil Ali-Jackson Kamil Ali-Jackson	Director	March 27, 2020

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
PDS Biotechnology Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of PDS Biotechnology Corporation and subsidiaries (the Company) as of December 31, 2019, the related consolidated statement of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the year ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these *consolidated* financial statements based on our audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provide a reasonable basis for our opinion.

(signed) KPMG LLP

We have served as the Company's auditor since 2019.

Short Hills, New Jersey
March 27, 2020

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
PDS Biotechnology Corporation:

Opinion on the Financial Statements
We have audited the accompanying balance sheets of PDS Biotechnology Corporation (the Company) as of December 31, 2018, and the related statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2018, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has negative cash flows from operations, negative working capital, and does not currently have revenue generating operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

/s/ Haynie & Company
Haynie & Company
Salt Lake City, Utah
March 5, 2019 (except for the Note 2, as to which the date is March 27, 2020)

We have served as the Company's auditor since 2018

PDS BIOTECHNOLOGY CORPORATION and Subsidiaries
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,161,739	$ 103,695
Prepaid expenses and other	2,308,462	18,428
Total current assets	14,470,201	122,123
Property and equipment, net	21,051	29,508
Other assets	–	12,800
Total assets	$ 14,491,252	$ 164,431
LIABILITIES AND STOCKHOLDERS' EQUITY LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,197,720	$ 1,307,529
Accrued expenses	1,097,640	601,889
Restructuring reserve	498,185	–
Total current liabilities	2,793,545	1,909,418
Noncurrent liability:		
Warranty liability	–	291,225
Convertible promissory notes payable	–	30,000
Total liabilities	2,793,545	2,230,643
STOCKHOLDERS' EQUITY		
Common stock, $0.00033 par value, 75,000,000 shares authorized at December 31, 2019 and December 31, 2018, 5,281,237 shares and 3,417,187 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	1,742	1,128
Additional paid-in capital	40,633,670	19,871,759
Accumulated deficit	(28,937,705)	(21,939,099)
Total stockholders' equity (deficit)	11,697,707	(2,066,212)
Total liabilities and stockholders' equity (deficit)	$ 14,491,252	$ 164,431

See accompanying notes to the consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2019	2018
Operating expenses:		
Research and development expenses	$ 6,099,580	$ 830,744
General and administrative expenses	10,981,765	2,788,016
Impairment expense IPRD	2,974,000	–
Lease termination costs	979,273	–
Depreciation and amortization	–	27,426
Total operating expenses	21,034,618	3,646,186
Loss from operations	(21,034,618)	(3,646,186)
Other income (expense):		
Gain on bargain purchase upon merger	13,334,568	–
Interest income	353,490	–
Interest expense	(33,559)	(3,595)
Other	–	(900)
Loss on extinguishment of debt	–	(185,800)
Loss before income taxes	(7,380,119)	(3,836,481)
Income taxes (benefit)	(381,513)	–
Net loss and comprehensive loss	$ (6,998,606)	$ (3,836,481)
Net loss per share, basic and diluted	$ 1.44	$ 1.15
Weighted average common shares outstanding basic and diluted	4,868,079	3,337,351

See accompanying notes to the consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional	Accumulated	Total
	Shares Issued	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance - December 31, 2017	**3,051,538**	**$ 1,007**	**$ 17,492,083**	**$ (18,102,618)**	**$ (609,528)**
Stock based compensation expense	–	–	251,947	–	251,947
Issuance of common stock, net of issuance costs	338,595	112	1,552,683	–	1,552,792
Issuance of common stock for warrant exercise	7,673	3	99,959	–	99,962
Issuance of common stock for stock option exercise	19,381	6	132,983	–	132,989
Warrant costs associated with stock issuance	–	–	342,104	–	342,104
Net loss	–	–	–	(3,836,481)	(3,836,481)
Balance - December 31, 2018	**3,417,187**	**1,128**	**19,871,759**	**(21,939,099)**	**(2,066,212)**
Stock based compensation expense	–	–	3,139,053	–	3,139,053
Issuance of common stock, net of issuance costs	48,930	16	749,984	–	750,000
Issuance of warrant in consideration for settlement agreement	–	–	372,925	–	372,925
Issuance of common stock for antidilution	97,960	32	(32)	–	–
Issuance of common stock for convertible debt	9,683	3	65,903	–	65,906
Issuance of common stock from equity transaction	100,654	33	603,891	–	603,924
Equity from merger transaction	1,599,178	528	15,793,109	–	15,793,637
Issuance of common stock from 401K match	7,645	2	37,078	–	37,080
Net loss	–	–	–	(6,998,606)	(6,998,606)
Balance - December 31, 2019	**5,281,237**	**$ 1,742**	**$ 40,633,670**	**$ (28,937,705)**	**$ 11,697,707**

See accompanying notes to the consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION and Subsidiaries
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (6,998,606)	$ (3,836,481)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,139,053	866,845
Issuance of common stock from equity transaction	603,924	–
Stock-based 401K company common match	37,080	–
Depreciation and amortization expense	98,414	69,118
Impairment charge - IPR&D	2,974,000	–
Deferred income tax benefit	(381,513)	–
Loss on extinguishment of debt	–	185,800
Loss on disposal of fixed asset	310,951	–
Write off of remaining ROU asset and lease liability pursuant to a lease termination	(32,309)	–
Bargain purchase gain	(13,334,568)	–
Interest expense from beneficial conversion feature	32,953	–
Increase in warranty liability	81,700	–
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,138,548)	35,027
Accounts payable	(1,977,667)	788,830
Accrued expenses and other liabilities	83,753	321,284
Restructuring reserve	(1,572,086)	–
Net cash used in operating activities	(18,073,469)	(1,569,577)
Cash flows from investing activities:		
Cash received in reverse merger transaction	29,106,513	–
Proceeds from sale of equipment	275,000	–
Net cash provided by investing activities	29,381,513	–
Cash flows from financing activities:		
Proceeds from issuance of common stock	750,000	1,280,000
Proceeds from stock option exercise	–	132,989
Proceeds from warrant exercise	–	99,962
Repayments of capital lease obligation	–	(15,563)
Net cash provided by financing activities	750,000	1,497,388
Net increase (decrease) in cash and cash equivalents	12,058,044	(72,189)
Cash and cash equivalents at beginning of period	103,695	175,884
Cash and cash equivalents at end of period	$ 12,161,739	$ 103,695
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ –	$ 1,362
Income taxes	$ –	$ 500
Supplemental cash flow information:		
Conversion of convertible notes and accrued interest into common stock	$ 32,953	$ –
Consideration in connection with reverse merger transaction	$ 15,793,638	$ –
Conversion of warranty liability into addtional common stock	$ 372,925	$ –

See accompanying notes to the consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION and Subsidiaries
Notes to Consolidated Financial Statements

Note 1 – Nature of Operations

PDS Biotechnology Corporation, a Delaware corporation (the "Company," "PDS" or the "combined company"), is a clinical stage immuno-oncology company with a growing pipeline of clinical-stage immunotherapies to treat cancer at various stages, including head and neck cancer, prostate cancer, breast cancer, cervical cancer, anal cancer, and other cancers. All of PDS's products are based on the proprietary Versamune ® platform technology, which activates and directs the human immune system to unleash a powerful and targeted attack against cancer cells. The Versamune®-based immunotherapies may be used as monotherapies or in combination with other agents. PDS is initially prioritizing the development of the Versamune®-based products as combination therapies to be administered with other potentially synergistic agents such as FDA-approved therapeutic or immunotherapeutic agents and promising therapeutic agents still in clinical development.

PDS has developed numerous patents and patent applications related to its Versamune ® platform. As of December 31, 2019, PDS holds four (4) U.S. patents with granted claims directed to its platform technology and six (6) pending patent applications. These issued patents will expire in 2025, 2031, 2031 and 2033, respectively. Should the more recently submitted patents currently in prosecution be issued, these will expire in 2033 through 2037 assuming no patent term extensions are granted. As of December 31, 2019, PDS holds twenty (22) issued foreign patents and thirty-three (33) pending foreign patent application which cover compositions of matter and methods of use related to its platform technology. These issued patents will expire in 2031-2034, or later if patent term extension applies.

Licensed patents

Licensed Patent Families 1 and 2 cover the Versamune ®-based product candidates, as they are directed to the currently utilized Versamune ® ingredient, (R)-DOTAP and its crystal forms, manufacturing methods, and pharmaceutical compositions using the compounds. PDS Biotechnology has an exclusive worldwide license from Merck & Cie to Licensed Patent Families 1 and 2, which are owned by Merck Patent GmbH, for use in the Company's immunotherapy compositions and immunotherapies. Licensed Patent Families 3 and 4 are licensed from the US government, and are directed to mucin-1 ("MUC-1") antigens to be used by the Company in future cationic lipid immunotherapy or vaccine products. Such immunotherapies can be used for treating a range of cancers, including colon, breast, ovarian and lung cancers.

Reverse acquisition

On March 15, 2019, the Company, then operating as Edge Therapeutics, Inc. ("Edge"), completed its reverse merger with privately held PDS Biotechnology Corporation ("Private PDS"), pursuant to and in accordance with the terms of the Agreement and Plan of Merger, dated as of November 23, 2018, as amended on January 24, 2019, by and among the Company, Echos Merger Sub, a wholly-owned subsidiary of the Company ("Merger Sub"), and Private PDS, whereby Private PDS merged with and into Merger Sub, with Private PDS surviving as the Company's wholly-owned subsidiary (the "Merger"). In connection with and immediately following completion of the Merger, the Company effected a 1-for-20 reverse stock split (the "Reverse Stock Split") and changed its corporate name from Edge Therapeutics, Inc. to PDS Biotechnology Corporation, and Private PDS changed its name to PDS Operating Corporation.

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally accepted accounting principles in the United States ("U.S. GAAP") and Private PDS is considered the accounting acquirer. Accordingly, upon consummation of the Merger, the historical financial statements of Private PDS became the Company's historical financial statements, and the historical financial statements of Private PDS are included in the comparative prior periods. See "Note 4 – Reverse Merger" for more information on the Merger. As part of the Merger, the Company acquired all of Edge's assets relating to current and future research and development.

Note 2 – Summary of Significant Accounting Policies

(A) **Use of estimates:**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses at the date of the consolidated financial statements and during the reporting periods, and to disclose contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates. The most significant estimates relate to the recognition and measurement of assets acquired and liabilities assumed in the business acquisition, assessment of indicators of impairment of intangible assets and the fair value of securities underlying stock-based compensation and other equity awards.

(B) **Significant risks and uncertainties:**

The Company's operations are subject to a number of factors that may affect its operating results and financial condition. Such factors include, but are not limited to: the clinical and regulatory development of its products, the Company's ability to preserve its cash resources, the Company's ability to add product candidates to its pipeline, the Company's intellectual property, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products if approved for sale, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products. As such, there can be no assurance that the Company's future research and development programs will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting its intellectual property.

(C) **Business acquisition:**

The Company's consolidated financial statements include the operations of an acquired business after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of IPR&D be recorded on the balance sheet. Transaction costs are expensed as incurred.

The Company measures certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value in the initial recognition of net assets acquired in a business combination and when measuring impairment losses. We estimate fair value using an exit price approach, which requires, among other things, that we determine the price that would be received to sell an asset or paid to transfer a liability in an orderly market. The determination of an exit price is considered from the perspective of market participants, considering the highest and best use of non-financial assets and, for liabilities, assuming that the risk of non-performance will be the same before and after the transfer.

When estimating fair value, depending on the nature and complexity of the asset or liability, we may use one or all of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.
- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.
- Cost approach, which is based on the cost to acquire or construct comparable assets, less an allowance for functional and/or economic obsolescence.

Our fair value methodologies depend on the following types of inputs:

- Quoted prices for identical assets or liabilities in active markets (Level 1 inputs).
- Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means (Level 2 inputs).
- Unobservable inputs that reflect estimates and assumptions (Level 3 inputs).

(D) **Cash equivalents and concentration of cash balance:**

The Company considers all highly liquid securities with a maturity weighted average of less than three months to be cash equivalents. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits.

(E) **Property and equipment:**

Property and equipment are recorded at cost. Depreciation is recorded for property and equipment using the straight-line method over the estimated useful lives of three to five years. The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable.

(F) **Research and development:**

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in the Company's research and development projects as well as fees paid to consultants and entities that perform certain research and testing on behalf of the Company.

(G) **Patent costs:**

The Company expenses patent costs as incurred and classifies such costs as general and administrative expenses in the accompanying statements of operations and comprehensive loss.

(H) **Intangibles asset and impairment:**

As part of the reverse merger transaction on March 15, 2019, the Company acquired an in-process research and development ("IPR&D") intangible asset valued at $2,974,000 using a discounted cash flow method. In determining the value of IPR&D, management considers, among other factors, the stage of completion of the project, the technological feasibility of the project, whether the project have an alternative future use, and the estimated residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives. The discount rate used is determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors reflecting the economic risk that the projected cash flows may not be realized.

The Company reviews all of its long-lived assets for impairment indicators throughout the year. The Company performs impairment testing for indefinite-lived intangible assets annually and for all other long-lived assets whenever impairment indicators are present. When necessary, the Company records charges for impairments of long-lived assets for the amount by which the fair value is less than the carrying value of these assets. The Company's impairment review process is described in Note 7.

(I) **Stock-based compensation:**

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, directors and non-employees to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. Prior to 2019, the Company estimated the stock-based compensation for common stock awards based on the number of awards granted and the fair value of its common stock on the grant date. In 2019, the Company did not grant any common stock awards.

The Company expenses the fair value of its stock-based compensation awards to employees and directors on a straight-line basis over the requisite service period, which is generally the vesting period. Prior to January 1, 2019, the Company estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Beginning on January 1, 2019, the Company recognizes forfeitures as they occur.

On January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. ASU 2018-07, Improvements to Non-employee Share-Based Payment Accounting, which expands the scope of ASC 718, Compensation—Stock Compensation to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. The adoption of ASU 2018-07 had no impact to the Company's consolidated financial statements.

(J) **Net loss per common share:**

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common stock shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because potentially dilutive securities would have an antidilutive effect as the Company incurred a net loss for the years ended December 31, 2019 and 2018.

The potentially dilutive securities excluded from the determination of diluted loss per share as their effect is antidilutive, are as follows:

	Year Ended December 31,	
	2019	2018
Stock options to purchase Common Stock	1,421,797	1,658,883
Warrants to purchase Common Stock	258,825	475,694
Total	1,680,626	2,134,577

(K) **Income taxes:**

The Company provides for deferred income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the future tax consequences attributable to net operating loss carryforwards and for differences between the financial statement carrying amounts and the respective tax bases of assets and liabilities. Deferred tax assets are reduced if necessary by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

(L) **Fair value of financial instruments:**

FASB ASC 820, Fair Value Measurement Disclosures, specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies.
- Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

(M) **Subsequent events:**

Subsequent events have been evaluated through the date these financial statements were issued. See Note 16.

(N) **New accounting standards not yet adopted:**

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) (“ASU 2018-13”). ASU 2018-13 modifies disclosure requirements related to fair value measurement and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. Early adoption is permitted. ASU 2018-13 also allows for early adoption of any removed or modified disclosures upon issuance of ASU 2018-13 while delaying adoption of the additional disclosures until their effective date. The Company is currently evaluating the potential impact of ASU on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40) (“ASU 2018-15”). ASU 2018-15 reduces complexity for the accounting for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). ASU 2018-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact of ASU 2018-15 on its consolidated financial statements .

(O) **New accounting standards adopted:**

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The Company adopted the new lease standard, as of January 1, 2019, using the optional transition method under which comparative financial information will not be restated and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease; did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. Furthermore, the Company did not have any leases impacted by ASC 842 on the adoption date. As part of the purchase price allocation from the reverse merger, the Company recorded a Right of Use asset and Liability of $1.4 million.

The new lease standard also provides practical expedients for an entity’s ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize right-of-use (“ROU”) assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (office building).

The Company determines if an arrangement is a lease at inception. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as operating costs and property taxes are expensed as incurred.

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting, which expands the scope of Topic 718, Compensation—Stock Compensation to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. On January 1, 2019, the Company adopted ASU 2018-07 and there was no impact to its financial statements.

(P) **Immaterial Correction of an Error in Prior Periods :**

During the quarter ended December 31, 2019, the Company identified errors related to the presentation of certain historical equity accounting and the treatment of certain expenses in the pre-merger period for private PDS. In accordance with Accounting Standards Codification (“ASC”) 250, *Accounting Changes and Error Corrections*, we evaluated the materiality of the errors from quantitative and qualitative perspectives and concluded that the errors were immaterial to the Company’s prior period interim and annual financial statements. Since these revisions were not material to any prior period interim or annual financial statements, no amendments to previously filed interim or annual periodic reports are required. Consequently, the Company has adjusted for these errors by revising its historical financial statements presented herein. The Company corrected this immaterial error by restating the 2018 consolidated financial statements and related notes included herein. The immaterial impacts of this error correction for the fiscal year ended December 31, 2018 were as follows:

A.For the year ended December 31, 2018, the Company determined that it incorrectly recognized patent license fees as intangible assets. The net effect of this error resulted in a reduction in net intangible assets of $41,692 and increases in research and development expenses, net loss and accumulated deficit of $41,692.

B.For the year ended December 31, 2018, the Company determined that it incorrectly recognized stock-based compensation expense for common stock awards that were granted to two Board Members in the fourth quarter of 2018. These awards were in lieu of payments for services performed by the Board Members through the grant date. The terms of the awards provided that they vested immediately. The Company amortized the stock-based compensation expense from October 2018 through March 15, 2019 instead of on the grant date. The net effect of these errors resulted in a reduction in prepaid expenses of $138,200 and increases to general and administrative expenses, net loss and accumulated deficit of $138,200.

C.For the year ended December 31, 2018, the Company determined that it incorrectly capitalized transaction costs related to a business combination and a consulting agreement. The net effect of these errors resulted in increases in net loss, general and administrative expenses, additional paid- in capital and accumulated deficit of $560,234.

D.For the year ended December 31, 2018, the Company determined that it incorrectly accounted for an extinguishment of a trade payable in accordance with ASC 470-50-40-2. Under ASC 470-50-40-2 the difference between the reacquisition price of the debt and the net carrying amount of the extinguished debt shall be recognized currently in income of the period of extinguishment as losses or gains and identified as a separate item. Gains and losses shall not be amortized to future periods. The reacquisition price includes the fair value of any assets transferred or equity securities issued. It also includes fees (which may include noncash fees) the reporting entity pays the original lender in connection with the extinguishment. The net effect of these errors resulted in an increase in warrant liability of $291,225; and increases in loss on extinguishment, net loss and accumulated deficit of $185,800 and a reduction in accounts payable of $105,425.

The following table sets forth the effect this immaterial error correction had on the Company's consolidated balance sheet as of December 31, 2018:

	Previously Reported	Year Ended December 31, 2018 Corrections		Restated
ASSETS				
Prepaid expenses and other receivables	$ 156,628	$ (138,200)	B	18,428
Total current assets	260,323	(138,200)		122,123
Intangible Assets, net	41,692	(41,692)	A	-
Total assets	$ 344,323	$ (179,892)		$ 164,431
Liabilities and Stockholders' (Deficit)				
Current Liabilities:				
Accounts payable	$ 1,412,954	$ (105,425)	D	$ 1,307,529
Total current liabilities	2,014,843	(105,425)		1,909,418
Warrant liability	-	291,225	D	291,225
Total liabilities	2,044,843	185,800		2,230,643
Stockholders' (Deficit)				
Additional paid in capital	19,312,548	560,234	C	19,872,782
Accumulated deficit	(21,013,173)	(41,692)	A	(21,939,099)
		(138,200)	B	
		(560,234)	C	
		(185,800)	D	
Total stockholders' (deficit)	(1,700,520)	(365,692)		(2,066,212)
Total liabilities and stockholders' (deficit)	$ 344,323	$ (179,892)		$ 164,431

The following table sets forth the effect this immaterial error correction had on the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2018:

	Previously Reported	Year Ended December 31, 2018 Corrections		Restated
Operating expenses:				
Research and development	$ 789,052	$ 41,692	A	$ 830,744
General and administrative	2,089,582	138,200	B	2,788,016
		560,234	C	
Total operating expenses	2,906,060	740,126		3,646,186
Loss from operations	(2,906,060)	(740,126)		(3,646,186)
Other income (expense):				
Loss on extinguishment of debt	-	(185,800)	D	(185,800)
	(4,495)	(185,800)		(190,295)
Net (loss)	$ (2,910,555)	$ (925,926)		$ (3,836,481)

The following table sets forth the effect this immaterial error correction had on the Company's consolidated statement of cash flows for the year ended December 31, 2018:

	Previously Reported	Year Ended December 31, 2018 Corrections		Restated
Cash flows from operating activities:				
Net loss	$ (2,910,555)	$ (41,692)	A	$ (3,836,481)
		(138,200)	B	
		(560,234)	C	
		(185,800)	D	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	27,426	41,692	A	69,118
Loss on extinguishment of debt		291,225	D	185,800
		(105,425)	D	
Changes in operating assets and liabilities:				
Accounts payable	788,830			
Prepaid expenses and other receivables	(101,825)	138,200	B	36,375
Net cash used in operating activities	(1,009,343)	(560,234)		(1,569,577)
Cash flows from finacing activities:				
Issuance costs	(560,234)	560,234	C	-
Net cash provided by financing activities	937,154	560,234		1,497,388
Net increase (decrease) in cash and cash equivalents	(72,189)	-		(72,189)
Cash and cash equivalents beginning of the year	175,884	-		175,884
Cash and cash equivalents end of the year	$ 103,695	$ -		$ 103,695

Note 3 – Liquidity and Capital Resources

As of December 31, 2019, the Company had $12.2 million of cash and cash equivalents, primarily provided by $29.1 million of pre-existing cash on Edge's balance sheets that the Company obtained as a result of the Merger. The Company's primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when the Company pays these expenses, as reflected in the change to the Company's outstanding accounts payable and accrued expenses.

On July 29, 2019, the Company entered into a common stock purchase agreement (the "Aspire Purchase Agreement") pursuant to which, the Company has the right, in its sole discretion, to present Aspire Capital Fund, LLC ("Aspire Capital") with a purchase notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of the Company's common stock per business day, in an aggregate amount of up to $20.0 million of the Company's common stock (the "Purchase Shares") over the term of the Aspire Purchase Agreement at a per share price equal to the lesser of the lowest sale price of the Company's common stock on the purchase date or the arithmetic average of the three lowest closing sale prices for the Company's common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date. The Company may sell an aggregate of 1,034,979 shares of its common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. The Company may sell additional shares of its common stock above the 19.99% limit provided that (i) it obtains stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of the Company's common stock on July 26, 2019. The minimum price at which the Company sell shares under the Aspire Purchase Agreement is $0.50. On July 29, 2019, the Company issued 100,654 shares of common stock to Aspire Capital as consideration for entering into the Aspire Purchase Agreement. The Company recorded the fair value of the shares at July 29, 2019 of $603,924 as an expense in the third quarter of 2019. The Company has not issued any shares of its common stock to Aspire Capital under the Aspire Purchase Agreement, aside from the 100,654 shares that were issued to Aspire Capital as consideration for entering into the Aspire Purchase Agreement (the "Commitment Shares"). Concurrently with the Aspire Purchase Agreement, the Company entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"). In accordance with the Registration Rights Agreement, on August 20, 2019 the Company filed a Registration Statement on Form S-1(File No. 333-232988) to cover the resale of the Commitment Shares and any Purchased Shares issuable to Aspire Capital under the Aspire Purchase Agreement. There is market uncertainty regarding the utilization of financing associated from the Aspire Purchase Agreement. As of December 31, 2019, no Purchase Shares were sold to Aspire Capital under the Aspire Purchase Agreement.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Annual Report on Form 10-K. The Company's budgeted cash requirements in 2020 and beyond include expenses related to continuing development and clinical studies. Based on the Company's available cash resources and cash flow projections as of the date the consolidated financial statements were available for issuance, which includes additional proceeds of $11.9 million from our February 2020 offering, the Company believes there are sufficient funds to continue operations and research and development programs for at least 12 months from the date of this report. Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. These financial resources may not be adequate to sustain its operations.

The Company plans to continue to fund its operations and capital funding needs through equity and/or debt financings. However, the Company cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its existing stockholders. The Company may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to its stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict the Company's operations. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, it may be required to delay, limit, reduce, or terminate its product development or future commercialization efforts or grant rights to develop and market immunotherapies that the Company would otherwise prefer to develop and market itself. Any of these actions could harm the Company's business, results of operations and prospects. Failure to obtain adequate financing also may adversely affect the Company's ability to operate as a going concern.

Note 4 – Reverse Merger

On March 15, 2019, the Company (then operating as Edge), Merger Sub and Private PDS completed the Merger in accordance with the Plan of Merger and Reorganization, dated as of November 23, 2018, as amended on January 24, 2019, pursuant to and in accordance with which Merger Sub merged with and into Private PDS, with Private PDS surviving as the Company's wholly-owned subsidiary. Immediately following completion of the Merger, the Company effected the Reverse Stock Split at a ratio of one new share for every twenty shares of its common stock then-outstanding, and changed its corporate name from Edge Therapeutics, Inc. to PDS Biotechnology Corporation, and Private PDS, now the Company's wholly-owned subsidiary, changed its name to PDS Operating Corporation. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

In connection with the Merger, each share of Private PDS's common stock outstanding immediately prior to the Merger was converted into 0.3262 shares (on a post-Reverse Stock Split basis) of the Company's common stock. As a result, the Company issued 3,573,760 shares of its common stock to the stockholders of Private PDS in exchange for all of the outstanding shares of common stock of Private PDS.

For accounting purposes, Private PDS is considered to be the accounting acquirer in the Merger because Private PDS's stockholders owned approximately 70% of the combined company's common stock immediately following the closing of the Merger. As the accounting acquirer, Private PDS's assets and liabilities continue to be recorded at their historical carrying amounts and the historical operations that will be reflected in the Company's consolidated financial statements will be those of Private PDS. All references in the consolidated financial statements to the number of shares and per share amounts of the Company's common stock have been retroactively restated to reflect completion of the Merger and the Reverse Stock Split.

Purchase Price

Pursuant to the Plan of Merger and Reorganization Agreement, as amended, Edge issued to Private PDS's stockholders a number of shares of Edge's common stock representing approximately 70% of the outstanding shares of common stock of the combined company. The purchase price, which represents the consideration transferred to Edge's stockholders in the Merger is calculated based on the number of shares of common stock of the combined company that Edge's stockholders owned as of the closing of the Merger on March 15, 2019, which consists of the following:

Number of shares of the combined company to be owned by Edge security holders (1)		1,600,166
Multiplied by the price per share of Edge's common stock as of March 15, 2019	$	9.87
Purchase price (in thousands)	$	15,794

(1) The amount includes 1,576,916 shares of Edge's common stock outstanding as of March 15, 2019 plus 23,250 stock options of Edge that were in the money and vested immediately upon closing of the Merger. At closing, 753 of in-the-money options and 235 fractional shares paid out in cash to shareholders were not issued as common stock, resulting in 1,599,178 common shares issued.

Final Purchase Price Allocation

The Company completed its analysis of the allocation of the purchase price. The purchase price was allocated to the net assets acquired of Edge based upon their preliminary estimated fair values as of March 15, 2019. The in-process research and development asset ("IPR&D") that is recognized relates to Edge's NEWTON 2 clinical trial for EG-1962 that has not reached technological feasibility. The Company was actively looking to license out EG-1962 and had preliminary discussions with third parties who were actively looking at the data of EG-1962 during the year. Accordingly, the IPR&D was capitalized as an indefinite-lived intangible asset and tested for impairment at least annually until it is determined that there is no future economic benefit from EG-1962. As a result of capitalizing the IPR&D, the Company recognized an indefinite life deferred tax liability. During the three months ended June 30, 2019, two adjustments were made to the preliminary allocation. The first was for $275,000 relating to an offer to purchase equipment that was given a value of $0 in the preliminary allocation. The second was for $65,551 relating to Edge's bonus plan that was effective prior to the date of acquisition. During the three months ended December 31, 2019 two additional adjustments were made to the preliminary valuation. The first was for an increase of $1,751,000 relating to the IPR&D in which the Company finalized the valuation of the IPR&D and as a result recognized an additional deferred tax liability of $224,513. The second was for a write-off relating to a transition service arrangement that was effective prior to the date of the acquisition for $131,250. In accordance with ASC 805, Business Combinations any the excess of the fair value of the acquired net assets over the purchase price has been recognized as a bargain purchase gain in the consolidated statement of operations and comprehensive loss. The Company has reassessed whether all the assets acquired, and the liabilities assumed have been identified and recognized in the purchase price allocation.

The final allocation of the purchase price to the net assets of Edge, based on the fair values as of March 15, 2019, is as follows:

Cash and cash equivalents	$ 29,106,513
Prepaid expense and other assets	1,585,482
Right to use asset	1,384,810
Intangible assets-IPR&D	2,974,000
Total identifiable assets acquired	35,050,805
Accounts payable, accrued expenses, other liabilities	(4,595,934)
Long term lease liability	(945,152)
Deferred income tax benefit	(381,513)
Total liabilities assumed	(5,922,599)
Net identifiable assets acquired	29,128,206
Bargain purchase gain	(13,334,568)
Purchase price	$ 15,793,638

The fair value of the IPR&D was determined using the discounted cash flow method based on probability- adjusted cash flow success scenarios to develop EG-1962 into a commercial product, estimating the revenue and costs. The rates utilized to discount the net cash flows to the present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections.

Pro Forma Financial Information

The following pro forma consolidated results of net loss for the years ended December 31, 2019 and 2018 assume the Merger was completed as of January 1, 2018:

	Year Ended December 31,	
	2019	2018
Pro forma operating expenses	$ (31,152,190	$ 46,742,753
Pro forma net loss	(31,134,293)	(44,704,487)
Pro forma basic and diluted net loss per share	$ (6.40)	$ (9.12)

The December 31, 2019 pro forma net loss excludes the bargain purchase gain that resulted from the Merger.

Note 5 – Fair Value of Financial Instruments

There were no transfers between Levels 1, 2, or 3 during the years ended December 31, 2019 or 2018.

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets (Level 1)	Quoted Prices in Inactive Markets (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2019:				
Cash and cash equivalents	$ 12,161,739	$ 12,161,739	$ –	$ –
As of December 31, 2018:				
Cash and cash equivalents	$ 103,695	$ 103,695	$ –	$ –
Warrant liability (See Note 12)	$ 291,225	$ –	$ –	$ 291,225

Note 6 – Property and Equipment

Property and equipment is summarized as follows:

	December 31,	
	2019	2018
Furniture and equipment	$ 14,964	$ 1,343
Computer and Telephone equipment	13,545	13,545
Lab equipment	86,911	86,911
Total furniture and equipment	115,420	101,799
Less accumulated depreciation	(94,369)	(72,291)
Property and equipment, net	$ 21,051	$ 29,508

Depreciation expense for the years ended December 31, 2019 and 2018 was $98,414 and $23,313, respectively.

Note 7 – Impairment Charge

During the three months ended December 31, 2019, the Company determined that the intangible asset related to Edge's NEWTON 2 clinical trial for EG-1962 was impaired due to significantly reduced activity in the data room and a lack of new interest from third parties to purchase or license the product. Further the Company does not have the internal resources to pursue EG 1962 as an internal development project and has stated publicly that it had intended to find a partner to fund and run the EG 1962 program. The drop off in interest from third parties and the lack of any new inbound interest has made this an extremely low probability of success. As a result for the year ended December 31, 2019, the Company recorded an impairment charge - IPR&D of $2,974,000 for the estimated value of the IPR&D asset of $2,974,000 in its consolidated statement of operations and comprehensive loss.

Note 8 – Leases

The Company adopted Accounting Standards Codification (ASC) Topic 842 on the date of the Merger and recognized an operating right-of-use (ROU) asset of $1.4 million and operating lease liabilities of $1.4 million at upon acquiring the lease in the reverse merger. The Company leases office space in Berkeley Heights, New Jersey that was expected to expire on November 15, 2021 under an operating lease. In addition to the monthly base amount in the lease agreement, the Company is required to pay its proportionate share of real estate taxes and operating expenses during the lease term which are expensed as incurred. The discount rate implicit within the lease is not determinable, therefore Company estimated an incremental borrowing rate based on the information available on the date of the Merger.

For the year ended December 31, 2019 the Company's operating lease expense was $ 247,368.

On July 8, 2019, the Company entered into a lease termination agreement for its office space located at 300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922 effective August 31, 2019 (the "Lease Termination Agreement"). Pursuant to the Lease Termination Agreement, the Company is required to pay 50% of the remaining lease payments of $665,802 over three installments on September 1, 2019, December 1, 2019 and March 1, 2020. On August 31, 2019, the right-of-use asset of $1.2 million and operating lease liability of $1.2 million was written off. In addition, a loss on lease termination of $0.6 million was recorded in office move expenses. Leasehold improvements amounting to approximately $0.3 million were also written off and are included in lease termination costs.

Note 9 – Accrued Expenses and Restructuring Reserve

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2019	2018
Accrued research and development costs	$ 16,415	$ 315,529
Accrued professional fees	256,062	177,417
Accrued compensation	603,229	45,833
Accrued rent	221,934	8,000
Accrued other	-	55,110
Total	$ 1,097,640	$ 601,889

Restructuring Reserve

Restructuring reserve relates to the severance costs incurred by Edge Therapeutics in 2019 prior to the merger transaction and assumed by the Company as part of the purchase accounting, but not yet paid. The severance costs continue through September 2020. The Company recorded a restructuring reserve of $2,070,271. For the year ended December 31, 2019, the Company paid $1,572,086 of restructuring expenses. As of December 31, 2019, the remaining restructuring reserve balance was $498,185.

Note 10 – Convertible Promissory Note

In November 2017, the Company received $30,000 from an investor in exchange for a convertible promissory note bearing interest at 7.50% per annum. The original terms of the promissory note was amended in December 2018 and states that in the event the Company consummates a sale of the Company prior to the conversion or repayment in full of this Note, the outstanding principal amount and all accrued but unpaid interest due shall automatically convert into the numbers of shares of the Company's common stock equal to (a) the principal amount plus all accrued but unpaid interest thereon, divided by the lesser of (a) $1.11 and (b) the parent closing price multiplied by the exchange ratio (each, as defined in the merger agreement of $3.22). This event occurred on March 15, 2019, the date of the Merger, and as a result, the outstanding principal amount of $30,000 and accrued unpaid interest of $2,950 was converted into 9,683 shares of the Company's common stock. At the date of the Merger the effective conversion price was less than the parent's closing stock price of $3.22. As a result, for the year ended December 31, 2019, the Company recorded a beneficial conversion charge of $32,953 which was recorded to interest expense in the consolidated statement of operations and comprehensive loss and an increase to additional paid in capital for the same amount in its consolidated statement of changes in stockholder's equity (deficit)..

Note 11 – Stock-Based Compensation

The Company has five equity compensation plans: the 2009 Amended Stock Plan, the 2010 Equity Incentive Plan, the 2012 Equity Incentive Plan, 2014 Equity Incentive Plan and the 2018 Stock Incentive Plan (the "Plans"). Originally, the Company was able to grant up to 27,410 and 54,820 shares of Common Stock as both incentive stock options ("ISOs") and nonqualified stock options ("NQs") under the 2010 Equity Incentive Plan and the 2012 Equity Incentive Plan, respectively. In 2013, the Company's stockholders approved an increase to 63,957 shares authorized for issuance under the 2010 Equity Incentive Plan. In 2014, the Board of Directors of the Company (the "Board") approved an increase to 67,520 shares authorized for issuance under the 2010 Equity Incentive Plan.

In 2014, the Company's stockholders approved the 2014 Equity Incentive Plan pursuant to which the Company may grant up to 91,367 shares as ISOs, NQs and restricted stock units ("RSUs"), subject to increases as hereafter described (the "Plan Limit"). In addition, on January 1, 2015 and each January 1 thereafter and prior to the termination of the 2014 Equity Incentive Plan, pursuant to the terms of the 2014 Equity Incentive Plan, the Plan Limit was and shall be increased by the lesser of (x) 4% of the number of shares of Common Stock outstanding as of the immediately preceding December 31 and (y) such lesser number as the Board of Directors may determine in its discretion. On January 1, 2016, 2017, 2018 and 2019 the Plan Limit was increased to 152,366 shares, 210,203 shares, 271,941 shares and 323,529 shares, respectively. In March 2019, the Plan was amended and restated which removed the annual increase component and was limited to 826,292 shares.

In 2018, the Company's stockholders approved the 2018 Stock Incentive Plan pursuant to which the Company may grant up to 558,071 shares as Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock, (iv) Preferred Stock, (v) Stock Reload Options and/or (vi) Other Stock-Based Awards.

Pursuant to the terms of the Plans, ISOs have a term of ten years from the date of grant or such shorter term as may be provided in the option agreement. Unless specified otherwise in an individual option agreement, ISOs generally vest over a four year term and NQs generally vest over a one to five year terms. Unless terminated by the Board, the Plans shall continue to remain effective for a term of ten years or until such time as no further awards may be granted and all awards granted under the Plans are no longer outstanding. As of December 31, 2019, there were 190,799 shares available for grant under the 2018 Stock Incentive Plan.

On June 17, 2019, the Board adopted the 2019 Inducement Plan. The 2019 Inducement Plan provides for the grant of non-qualified stock options. The 2019 Inducement Plan was recommended for approval by the Compensation Committee of the Board and subsequently approved and adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Board has reserved 200,000 shares of the Company's common stock for issuance pursuant to non-qualified stock options granted under the 2019 Inducement Plan, and the 2019 Inducement Plan will be administered by the Compensation Committee of the Board. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, non-qualified stock options under the 2019 Inducement Plan may only be made to an employee who has not previously been an employee or member of the Board (or any parent or subsidiary of the Company), or following a bona fide period of non-employment by the Company (or a parent or subsidiary of the Company), if he or she is granted such non-qualified stock options 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. As of December 31, 2019, there were 126,500 shares available for grant under the 2019 Inducement Plan.

The following table summarizes the components of stock-based compensation expense in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Research and development	$ 550,605	$ 46,383
General and administrative	2,588,448	205,564
Total	$ 3,139,053	$ 251,947

The following table summarizes the stock option activity for the Company' stock option plans for the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance at January 1, 2019	541,117	$ 7.20	4.29	$ –
Assumed in connection with merger	347,697	$ 121.52	5.67	$ –
Granted	828,637	$ 7.43	9.35	$ –
Exercised	-	$ -	–	$ –
Forfeited	(295,654)	$ 99.27	-	$ -
Options outstanding at December 31, 2019	1,421,797	$ 15.95	7.09	$ -
Vested and expected to vest at December 31, 2019	1,421,797	$ 15.95	7.09	$ -
Exercisable at December 31, 2019	1,000,367	$ 20.15	6.03	$ –

As of December 31, 2019 there was approximately $1,681,000 of unamortized stock compensation expense, which is expected to be recognized over a remaining average vesting period of 3.38 years.

The weighted-average grant date fair value of the stock options granted in 2019 was $5.67 per share.

The fair value of options granted during the year ended December 31, 2019 was estimated using the Black-Scholes option valuation model utilizing the following assumptions:

	Year Ended December 31, 2019
	Weighted Average
Volatility	85% - 94%
Risk-Free Interest Rate	1.49% - 2.43%
Expected Term in Years	5.54 years
Dividend Rate	–

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available.

Risk-free interest rate. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

Expected term. The expected term represents the period options are expected to be outstanding. The expected term of the options is based on using the simplified method, which is the midpoint between the requisite service period and the contractual term of the option, since the Company has a limited history of being a public company from March 15, 2019 (the date of the Merger) to develop reasonable expectations about future exercise patterns and employment duration for the stock options grants.

Expected dividend rate. The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

Note 12 - Stockholders' Equity (Deficit)

Preferred Stock

The Company currently has 5,000,000 shares of preferred stock authorized.

Voting

Shares of preferred stock may be issued in one or more series, from time to time, with each such series to consist of such number of shares and to have such voting powers relative to other classes or series of preferred stock, if any, or common stock, full or limited or no voting powers, and such designations, preferences and relative, participating, optional or other special rights, and such qualifications, limitations or restrictions thereof, as shall be stated in the resolution or resolutions providing for the issuance of such series adopted by the Company's Board of Directors.

Common Stock

The Company currently has 75,000,000 shares of common authorized.

Voting

Each holder of a share of common stock is entitled to one vote for each share of common stock.

Dividends

Dividends may be declared and paid as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding preferred stock.

Preemptive Rights.

The holders of common stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Company whether now or hereafter authorized.

Liquidation Rights

Upon the dissolution or liquidation of the Company, whether voluntary or involuntary, holders of the common stock will be entitled to receive all assets of the Company available for distribution to its stockholders, subject to any preferential rights of any then outstanding preferred stock.

2019 Issuance of Common Stock

In January 2019, Private PDS's Board of Directors approved an amendment to the terms of the 2018 financing. The amendment increased the warrant coverage (which is the amount of warrants each investor is entitled to based on how much they paid for the common stock) from 20% to 45% in connection with the 2018 bridge financing term sheet. As a result of the amendment, in 2019 investors who purchased shares of common stock in 2018 received an additional $32,500 in warrant coverage. In February 2019, Private PDS issued 48,930 shares of common stock resulting in proceeds of $750,000 and the investors collectively received a warrant coverage of $337,500. The exercise price of the warrants to purchase shares of Private PDS's common stock is $9.87, which is the stock price as of the date of the Merger. Accordingly, during the year ended December 31, 2019, Private PDS issued 37,487 warrants to purchase shares of Private PDS's common stock. These warrants were determined to be equity instruments under ASC 480, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging.

Warrant Liability Classified to Additional Paid in Capital

On March 13, 2019, in connection with the settlement agreement entered into with one of its vendors, Private PDS granted a warrant to purchase 45,288 shares of its common stock at an exercise price of $9.87 which is the stock price as of the date of the Merger. At March 13, 2019, the estimated fair value of the warrant was $372,925. As a result, at March 13, 2019, Private PDS marked the warrant liability to the estimated fair value by $81,700 from $291,225 at December 31, 2018 to $372,925 and recorded an increase to general and administrative expenses in its statement of operations in 2019 for the $81,700. Since Private PDS issued a fixed number of warrants and a fixed exercise price to the vendor the warrant liability of $372,925 was classified to additional paid in capital.

At March 13, 2019, Private PDS estimated the fair value of the warrant using the Black-Scholes option pricing model utilizing the following assumptions. Private PDS determined the expected stock price volatility based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available. The expected term of the warrant was based on the contractual term. The risk-free interest rate was based on the U.S. Treasury yield curve at the time of the grant over the term of the warrant grant. The expected dividend rate is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

Volatility		83%
Risk-Free Interest Rate		2.63%
Expected Term in Years		10
Dividend Rate		0.00%
Fair Value of Warrant	$	8.23

Note 13 – Income Taxes

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory rate	21.0%	21.0%
State taxes	21.1%	5.4%
Extraordinary Gain	38.0%	–
Permanent differences	(4.1)%	(1.8)%
Research and development	4.1%	0.2%
Valuation allowance	(74.6)%	(24.8)%
Other	(0.3)%	–
Effective tax rate	5.2%	–

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	December 31,	
	2019	2018
Federal net operating losses	$ 16,620,765	$ 5,147,280
State net operating losses	4,653,462	–
Stock options	2,153,487	–
Warrants	143,841	–
Federal tax credit	740,040	–
State tax credits	657,376	–
Amortization	47,811	2,238
Accrued expense	363,617	–
Depreciation	719,263	438
In-process R&D	–	98,427
Other	18,098	–
Total gross deferred tax assets	26,117,760	5,248,383
Less valuation allowance	(26,117,760)	(5,248,383)
Net deferred tax assets	$ –	$ –

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence to determine whether it is more likely than not that some portion of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. At December 31, 2019 and 2018, the Company has recorded a full valuation allowance against its net deferred tax assets of approximately $26.1 and $5.2 million respectively. The change in the valuation allowance during the year ended 2019 was approximately $20.8 million.

At December 31, 2019, the Company had federal net operating loss ("NOL") carryforwards of approximately $79.1 million. At December 31, 2019, the Company had federal research and development credit carryforwards of approximately $0.7 million. The federal net operating loss carryforwards begin to expire in 2028, losses generated in 2018 or later will carry forward indefinitely. The federal credit carryforwards begin to expire in 2032. Section 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event certain ownership changes, as defined. The Company may be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited

At December 31, 2019, the Company had approximately $65.4 million of State of New Jersey NOLs which expire between 2029 and 2039. At December 31, 2019, the Company had approximately $0.8 million of the State of New Jersey research development credits carryforwards. The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net loss carryforwards. The Technology Business Tax Certificate Transfer Program enables qualified, unprofitable NJ-based technology or biotechnology companies with fewer than 225 US employees (including parent company and all subsidiaries) to sell a percentage of New Jersey NOLs and research and development ("R&D") tax credits to unrelated profitable corporations. In 2019, the Company did not qualify for the program. There is no certainty as to whether this program will continue.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2019, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2009 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2019 and 2018.

Note 14 – Commitments and Contingencies

Employment Matters

The Company has entered into employment agreements or offer letters with each of its executive officers. The employment agreements generally provide for, among other things, salary, bonus and severance payments. The employment agreements generally provide for between 12 months and 24 months of severance benefits to be paid to an executive (as well as certain potential bonus, COBRA and equity award benefits), subject to the effectiveness of a general release of claims, if the executive terminates his or her employment for good reason or if the Company terminates the executive's employment without cause. Such severance payments may be provided for as long as 24 months in connection with a termination following a change of control. The continued provision of severance benefits is conditioned on each executive's compliance with the terms of the Company's confidentiality and invention and assignment agreement as well as his or her release of claims.

Rent

For the years ended December 31, 2019 and 2018, rent was $113,009 and $53,441, respectively , for month-to-month arrangements not impacted by the adoption of ASC 842.

Note 15 – Retirement Plan

The Company has a 401(k) defined contribution plan for the benefit for all employees and permits voluntary contributions by employees subject to IRS-imposed limitations. The 401K employer contribution for the years ended December 31, 2019 and 2018 plan years were $37,080 and $0 respectively.

Note 16 – Subsequent Events

In February 2020, the Company completed an underwritten public offering, in which the Company sold 10,000,000 shares of common stock at a public offering price of $1.30 per share. The shares sold included 769,230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price. The Company received gross proceeds of approximately $13 million and net proceeds of approximately $11.9 million after deducting underwriting discounts and commissions.

On March 10, 2020, we entered into a sublease agreement, effective as of March 5, 2020, to occupy the office space located at 25B Vreeland Road, Suite 300, Florham Park, NJ. The sublease commences on May 1, 2020 and continues for a term of approximately forty (40) months with an option to renew through October 31, 2027. On March 17, 2020, the master lessor provided its consent to the sublease in accordance with the terms of the sublease.