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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 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.)

300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922
(Address of principal executive offices)

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

Edge Therapeutics, Inc.
(Former name, former address and former fiscal year, if changed since last report)

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 and post 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 Securities Exchange Act of 1934.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller Reporting Company ☒

Emerging growth company ☒

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

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

The number of shares of the registrant's Common Stock, par value $0.00033 per share, outstanding as of May 8, 2019 was 5,177,487.

PDS BIOTECHNOLOGY CORPORATION

FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2019

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As previously disclosed, on March 15, 2019, PDS Biotechnology Corporation (f/k/a Edge Therapeutics, Inc.), a Delaware corporation (the "Company"), completed the merger (the "Merger") of its wholly owned subsidiary, Echos Merger Sub, ("Merger Sub"), with and into privately held PDS Biotechnology Corporation, a Delaware corporation ("Private PDS"), 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, Merger Sub and Private PDS (the "Merger Agreement"). As a result of the Merger, Private PDS, the surviving company in the Merger, became a wholly-owned subsidiary of the Company. Following the Merger, the Company 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, Private PDS's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

This quarterly report on Form 10-Q relates to the Company's quarter ended March 31, 2019, which includes the date of the completion of the Merger, and is therefore the Company's first periodic report that includes results of operations for the combined company, including Private PDS.

Unless the context otherwise requires, references to the "Company," the "combined company" "we," "our" or "us" in this report refer to PDS Biotechnology Corporation and its subsidiaries; references to "PDS" refer to the Company following the completion of the Merger, references to "Edge" refer to the Company prior to the completion of the Merger, references to "Private PDS" refer to privately held PDS Biotechnology Corporation prior to the completion of the Merger, and references to "PDS Operating Corporation" refer to PDS Operating Corporation, the Company's wholly-owned subsidiary following the Merger.

Except as otherwise noted, references to "common stock" in this report refer to common stock, par value $0.00033 per share, of the Company. On March 15, 2019, the Company effected a 1-for-20 reverse split of its common stock. Unless noted otherwise, any share or per share amounts in this report, the accompanying unaudited condensed consolidated financial statements and related notes give retroactive effect to both the Merger and the reverse stock split.

This report contains the following trademarks, trade names and service marks of ours: Versamune® All other trade names, trademarks and service marks appearing in this quarterly report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms appear without the trade name, trademark or service mark notice for convenience only and should not be construed as being used in a descriptive or generic sense.

This quarterly report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are subject to the safe harbor created by those sections. For more information, see "Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Cautionary Note Regarding Forward-Looking Statements."

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Balance Sheets

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,592,845	$ 103,695
Prepaid expenses and other current assets	1,313,931	156,628
Total current assets	27,906,776	260,323
Property and equipment, net	412,735	29,508
Intangible assets, net	1,223,000	41,692
Right-to-use assets	1,347,557	–
Other assets	155,670	12,800
Total assets	$ 31,045,738	$ 344,323
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	$ 2,665,266	$ 1,412,951
Accrued expenses	446,962	601,889
Restructuring reserve	1,948,596	–
Operating lease liability- short term	477,300	–
Total current liabilities	5,538,124	2,014,840
Noncurrent liability:		
Deferred tax liability	157,000	–
Operating lease liability- long term	902,972	–
Convertible promissory notes payable	–	30,000
STOCKHOLDERS' EQUITY		
Preferred stock, 5,000,000 shares authorized at March 31, 2019 and December 31, 2018, 0 outstanding	–	–
Common stock, $0.00033 par value, 75,000,000 shares authorized at March 31, 2019 and December 31, 2018, 5,172,938 shares and 3,417,187 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	1,707	1,128
Additional paid-in capital	38,642,411	19,311,529
Accumulated deficit	(14,196,476)	(21,013,174)
Total stockholders' equity	24,447,642	(1,700,517)
Total liabilities and stockholders' equity	$ 31,045,738	$ 344,323

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development expenses	$ 1,030,003	$ 201,138
General and administrative expenses	3,905,877	535,801
Total operating expenses	4,935,880	736,939
Loss from operations	(4,935,880)	(736,939)
Other income (expense):		
Gain on bargain purchase	11,729,882	–
Interest income	23,302	6
Interest expense	(606)	(959)
Net income (loss) and comprehensive income (loss)	$ 6,816,698	$ (737,892)
Per share information:		
Net income (loss) per share , basic	$ 1.82	$ (0.24)
Net income (loss) per share , diluted	$ 1.47	$ (0.24)
Weighted average common shares outstanding, basic	3,748,325	3,099,311
Weighted average common shares outstanding, diluted	4,625,295	3,099,311

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares Issued	Amount			
Balance - December 31, 2017	3,051,538	$ 1,007	$ 17,492,083	$ (18,102,618)	$ (609,528)
Stock-based compensation expense	–	–	7,015	–	7,015
Capitalized offering costs	–	–	(44,000)	–	(44,000)
Issuance of common stock, net of issuance costs	281,860	93	757,801	–	757,894
Warrant costs associated with stock issuance	–	–	342,105	–	342,105
Net loss	–	–	–	(737,892)	(737,892)
Balance - March 31, 2018	3,333,398	$ 1,100	$ 18,555,004	$ (18,840,510)	$ (284,406)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares Issued	Amount			
Balance - December 31, 2018	3,417,187	$ 1,128	$ 19,311,529	$ (21,013,174)	$ (1,700,517)
Stock-based compensation expense	–	–	2,754,871	–	2,754,871
Issuance of common stock, net of issuance costs	48,930	16	749,984	–	750,000
Issuance of common stock for antidilution	97,960	32	(32)	–	–
Issuance of common stock for convertible debt	9,683	3	32,950	–	32,953
Equity from merger transaction	1,599,178	528	15,793,109	–	15,793,637
Net income	–	–	–	6,816,698	6,816,698
Balance - March 31, 2019	5,172,938	$ 1,707	$ 38,642,411	$ (14,196,476)	$ 24,447,642

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	$ 6,816,698	$ (737,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,754,871	7,015
Stock-based 401K company common match	–	–
Depreciation expense	18,958	7,231
Bargain purchase gain	(11,729,882)	–
Changes in assets and liabilities:		
Prepaid expenses and other assets	(181,679)	15,272
Accounts payable	(620,212)	16,014
Accrued expenses	(304,441)	288,022
Restructuring reserve	(121,675)	–
Net cash used in operating activities	(3,367,362)	(404,338)
Cash flows from investing activities:		
Cash received in reverse merger transaction	29,106,512	–
Net cash used in investing activities	29,106,512	–
Cash flows from financing activities:		
Payments for capital lease obligation	–	(3,478)
Proceeds from issuance of common stock, net of issuance costs	750,000	1,055,999
Net cash provided by financing activities	750,000	1,052,521
Net increase in cash	26,489,150	648,183
Cash and cash equivalents at beginning of period	103,695	175,884
Cash and cash equivalents at end of period	$ 26,592,845	$ 824,067
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ 150	$ 405
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	$ –

See accompanying notes to the condensed consolidated financial statements.

PDS Biotechnology Corporation
Notes to Condensed Consolidated Financial Statements (Unaudited)

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 various early-stage and late-stage cancers, 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.

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 3 – 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.

From the Company's inception, it has devoted substantially all of its efforts to business planning, engaging regulatory, manufacturing and other technical consultants, acquiring operating assets, planning and executing clinical trials and raising capital.

Note 2 – Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at March 31, 2019, the statements of operations and comprehensive income and loss for the three months ended March 31, 2019 and 2018, and cash flows for the three months ended March 31, 2019 and 2018 are unaudited. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, and following the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of its financial information. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The balance sheet as of December 31, 2018 included herein was derived from the audited condensed consolidated financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Private PDS audited financial statements and notes thereto as of and for the year ended December 31, 2018, filed by the Company with the SEC in its Current Report on Form 8-K/A on April 30, 2019.

(B) Use of estimates:

The preparation of 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 disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(C) 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 Company's review of strategic alternatives, 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.

(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) 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 various entities that perform certain research and testing on behalf of the Company.

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.

(F) 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.

(G) Intangibles:

The Company's intangible assets as of March 31, 2019 consist of in-process research and development ("IPR&D") intangible assets acquired as part of the reverse merger transaction on March 15, 2019. The fair value of IPR&D was preliminarily determined as of the acquisition date using a discounted cash flow method and subject to ongoing assessment within the valuation period. In determining the value of IPR&D, management considers, among other factors, the stage of completion of the projects, the technological feasibility of the projects, whether the projects 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 its IPR&D at least annually for possible impairment. IPR&D is reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the IPR&D below their carrying values. The Company tests its IPR&D each year on October 1. The Company's IPR&D asset totaled $1.2 million at March 31, 2019.

There were no trigger events during the three months ended March 31, 2019 to which an impairment analysis would be warranted.

(H) Stock-based compensation:

Pre merger, the Company measured and recognized share-based compensation expense, for both employee and director option awards, based on the grant date fair value of the awards. The Company recognized share-based compensation expense, net of estimated forfeitures, on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The Company determined the fair value of share-based awards granted to non-employees as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. All issuances of equity instruments issued to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. These awards were recorded in expense and additional paid-in capital in shareholders' equity (deficit) over the applicable service periods based on the fair value of the options at the end of each period.

The Company classified share-based compensation expense in its condensed consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company estimated the fair value of employee and director share options as of the date of grant using the Black-Scholes option pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimated its expected share price volatility based on the historical volatility of a publicly traded set of peer companies. The expected term of the Company's share options had been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the yield curve of a zero-coupon U.S. Treasury bond on the date of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield was based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

The Company also estimated the fair value of consultant and non-employee share options using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee and director options in each of the reporting periods, other than the expected life, which is assumed to be the remaining contractual life of the options.

Prospectively, the Company will measure employee stock-based awards at grant-date fair value and recognize employee compensation expense on a straight-line basis over the vesting period of the award.

Determining the appropriate fair value of stock-based awards will require the input of subjective assumptions, including, for stock options, the expected life of the option, and expected stock price volatility. The Company will use the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options will be estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and employment duration for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company will utilize comparable public companies and company specific as a basis for its expected volatility to calculate the fair value of options grants. The risk-free interest rate will be based on U.S. Treasury notes with a term approximating the expected life of the option.

(I) Common stock warrants:

The Company measures and recognizes warrants, for non-employees for the value or goods or services received or in conjunction with the issuance of a debt or equity financing issuance based on the grant date fair value of the warrant.

The Company determines the fair value of warrants granted to non-employees or investors as either the fair value of the consideration received or the fair value of the debt or equity instruments issued, whichever is more reliably measurable. All issuances of debt and equity instruments issued to investors or non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the debt and equity instruments issued. These awards can be recorded as either an expense or liability depending on the nature of the warrant.

Generally, if a warrant cannot be settled in cash by the holder or a stock settled transaction, the warrant is considered an equity transaction to the Company and has an offsetting debit to additional paid-in capital in shareholders' (deficit) equity based on the fair value of the warrant at the issuance date.

The Company estimates the fair value of warrants as of the date of grant using the Black-Scholes option pricing model as described in Stock-Based Compensation in the previous section.

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

Basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. All participating securities are excluded from basic weighted-average common shares outstanding. In computing both basic net income (loss) per share attributable to common stockholders and diluted net income (loss) per share attributable to common stockholders, undistributed earnings are re-allocated to reflect the potential impact of dilutive securities, including stock options and warrants. Diluted net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common equivalent shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders includes any dilutive effect from outstanding stock options and warrants using the treasury stock method.

The common stock issuable upon the conversion or exercise of the following dilutive securities as of March 31, 2018 has been excluded from the diluted net loss per share attributable to common stockholders calculation because their effect would have been antidilutive for the period presented:

	As of March 31, 2018
Stock options to purchase Common Stock	513,534
Convertible promissory note	9,051
Warrants to purchase Common Stock	115,860
Total	638,445

The following is a reconciliation of the numerator (net income or loss) and the denominator (number of shares) used in the calculation of basic and diluted net income (loss) per share attributable to common stockholders:

	Three Months Ended March,	
	2019	2018
Numerator		
Basic and diluted net income (loss)	$ 6,816,698	$ (737,892)
Denominator		
Shares used in computing basic net income (loss) per share	3,748,325	3,099,311
Shares from dilutive securities	876,970	–
Shares used in computing diluted net income (loss) per share	4,625,295	3,099,311
Net income (loss) per share, basic	$ 1.82	$ (0.24)
Net income (loss) per share, diluted	$ 1.47	$ (0.24)

(K) Accounting standards not yet adopted:

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 the new guidance.

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 the new guidance.

(L) 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 record 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.

ASU 2018-07, Improvements to Nonemployee Share Based Payment Accounting, eliminates the separate accounting model for nonemployee share-based payment awards and generally requires companies to account for share-based payment transactions with nonemployees in the same way as share-based payment transactions with employees. PDS adopted this ASU on January 1, 2019 and there was not a material impact requiring the retrospective adjustment to retained earnings on transition.

Note 3 – 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 financial statements will be those of Private PDS. All references in the unaudited interim condensed 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.

Preliminary Purchase Price Allocation

The preliminary 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 is actively looking to license out EG-1962 and has had preliminary discussions with third parties who are actively looking at the data of EG-1962. Accordingly, the IPR&D is 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. The preliminary allocation of the purchase price was based upon a preliminary valuation and the estimates and assumptions are subject to change. The area of the preliminary purchase price allocation that is not yet finalized relates to the fair value of the IPR&D and the related deferred tax liability. In accordance with Accounting Standards Codification ("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 condensed consolidated statement of operations. Any change to the initial estimate of the IPR&D and the related deferred tax liability will be recognized as an adjustment to the bargain purchase gain. The Company has reassessed whether all the assets acquired and the liabilities assumed have been identified and recognized in the preliminary purchase price allocation.

The allocation of the preliminary 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	1,441,732
Right to use asset	1,384,810
Intangible assets-IPR&D	1,223,000
Total identifiable assets acquired	33,156,055
Accounts payable, accrued expenses, other liabilities	(4,530,383)
Lease liability	(945,152)
Deferred tax liability	(157,000)
Total liabilities assumed	(5,632,535)
Net identifiable assets acquired	27,523,520
Bargain purchase gain	(11,729,882)
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 three months ended March 31, 2019 and 2018 assume the Merger was completed as of January 1, 2018:

	Three Months Ended March 31,	
	2019	2018
Pro forma operating expenses	$ 15,053,452	$ 20,833,121
Pro forma net loss	(15,714,303)	(21,577,995)
Pro forma basic and diluted net loss per share	$ (4.19)	$ (4.64)

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

Note 4 – Fair Value of Financial Instruments

There were no transfers among Levels 1, 2, or 3 during 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 March 31, 2019: (unaudited)				
Cash and cash equivalents	$ 26,592,845	$ 26,592,845	$ –	$ –
As of December 31, 2018:				
Cash and cash equivalents	$ 103,695	$ 103,695	$ –	$ –

Note 5 – Intangible Assets

As of March 31, 2019, $1,223,000 was for IPR&D resulting from the Merger's preliminary purchase price allocation. See Note 3.

As of December 31, 2018, the balance of $41,692 consisted of NIH licensing fees. This balance was expensed into research and development costs during the three months ended March 31, 2019.

Note 6 – Leases

We 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 adoption. The Company leases office space in Berkeley Heights, New Jersey which expires on November 15, 2021 under an operating lease. The Company has the option to renew the lease for five years. The Company evaluated the renewal option at the lease commencement date to determine if it is reasonably certain to excise the option. The lease provides for an initial monthly base amount plus annual escalations through the term of the 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. The discount rate used to measure the operating lease liability as of March 31, 2019 was 10.15%.

For the three months ended March 31, 2019, the Company's operating lease expense was $24,662.

As of March 31, 2019, other information related to the operating lease are as follows:

Cash paid for amounts included in measurement of lease liabilities:	
Operating cash flows for operating lease	$ 49,324
Right-of-use asset obtained in exchange for new operating lease liability	$ 1,384,810
Remaining lease term - operating lease liability	2.7
Discount rate - operating lease	10.15%

Reported as of March 31, 2019	
Current portion of operating lease liability	$ 477,300
Operating leases, net of current portion	902,972
Total	$ 1,380,272

Future minimum lease payments under non-cancelable operating leases as of March 31, 2019 were as follows:

Year ended December 31,	
2019 (excluding the three months ended March 31, 2019)	$ 445,193
2020	603,371
2021	530,386
Total future minimum lease payments	1,578,950
Less imputed interest	(198,678)
Total	$ 1,380,272

Note 7 – Accrued Expenses and Restructuring Reserve

Accrued expenses and other liabilities consist of the following:

	As of March 31, 2019	As of December 31, 2018
Accrued research and development costs	$ 172,190	$ 71,329
Accrued professional fees	221,528	421,617
Accrued compensation	45,244	54,269
Accrued other	–	46,674
Accrued rent	8,000	8,000
Total	$ 446,962	$ 601,889

Restructuring Reserve

	As of March 31, 2019	As of December 31, 2018
Restructuring reserve (1)	$ 1,948,596	$ –
Total	$ 1,948,596	$ –

(1) Restructuring reserve relates to the severance costs incurred by Edge Therapeutics prior to the merger transaction and assumed by the Company as part of the purchase accounting, but not yet paid. For the three months ended March 31, 2019, the Company incurred $121,675 of restructuring expense which is recognized within general and administrative expense.

Note 8 – Convertible Promissory Note

In November 2017, the Company received $30,000 from an investor in exchange for a convertible promissory note (2017 issuances). The 2017 issuances bear 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 (b) $3.40, which shall be automatically issued to Holder as of immediately prior to the consummation of such Sale of the Company. This event occurred on March 15, 2019, the date of the Merger, on which 9,683 shares of common stock were issued.

Note 9 – 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 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) Deferred 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.

The Company's stock-based compensation expense was recognized in operating expense as follows:

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
Stock-Based Compensation		
Research and development	$ 440,700	$ 3,219
General and administrative	2,314,171	3,796
Total	$ 2,754,871	$ 7,015

The fair value of options and warrants granted during the three months ended March 31, 2019 was estimated using the Black-Scholes option valuation model utilizing the following assumptions:

	Three Months Ended March 31,	
	2019	2018
	Weighted Average	Weighted Average
	(unaudited)	
Volatility	83.00%	0.00%
Risk-Free Interest Rate	2.49%	0.00%
Expected Term in Years	6.25	–
Dividend Rate	0.00%	0.00%
Fair Value of Option on Grant Date	$ 6.54	$ –

No grants were issued for the three months ended March 31, 2018.

The following table summarizes the number of options outstanding and the weighted average exercise price:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at December 31, 2018	541,117	$ 7.20		
Assumed in connection with Merger	347,697	121.52		
Granted	389,707	9.04		
Exercised	–	–		
Forfeited	(55,521)	5.01		
Options outstanding at March 31, 2019	1,223,000	$ 40.39	6.52	$ 357,168
Vested and expected to vest at March 31, 2019	1,223,000	$ 40.39	6.52	$ 357,168
Exercisable at March 31, 2019	1,223,000	$ 40.39	6.52	$ 357,168

At March 31, 2019 there was approximately $0 of unamortized stock option compensation expense, which is expected to be recognized over a remaining average vesting period of 0.00 years resulting from all options being fully vested and expensed as of the Merger on March 15, 2019.

Note 10 – Income Taxes

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 or all 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. The Company expects to have a loss for 2019 and there will be no current income tax expense. Additionally, there was a full valuation allowance against the net deferred tax assets as of March 31, 2019 and December 31, 2018. As such, the Company recorded no income tax benefit due to realization uncertainties.

The Company's U.S. statutory rate is 21%. The primary factor impacting the effective tax rate for the three months ended March 31, 2019 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

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, 2018, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception 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. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the three months ended March 31, 2019 and for the year ended December 31, 2018.

Note 11 – Commitments and Contingencies

Class Action Civil Litigation

From time to time in the ordinary course of the Company's business, the Company is subject to claims, legal proceedings and disputes.

On April 23, 2018, a purported securities class action complaint was filed against Edge, Brian Leuthner (Edge's President and Chief Executive Officer) and Andrew Saik (Edge's Chief Financial Officer and the Company's current Chief Financial Officer) in the United States District Court for the District of New Jersey, captioned *Sanfilippo v. Edge Therapeutics, Inc.*, Case No. 2:18-cv-8236. The complaint alleged that Edge, Mr. Leuthner and Mr. Saik violated Section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements concerning Edge's business, operations and prospects by failing to disclose that EG-1962 would likely fail a futility analysis. The complaint also asserted a "control" person claim against Mr. Leuthner and Mr. Saik pursuant to Section 20(a) of the Exchange Act. The complaint was brought on behalf of all purchasers of Edge's common stock between December 27, 2017 and March 27, 2018, and sought unspecified damages. On December 7, 2018, the court appointed Sam Kirkpatrick and Amos Bakouple lead plaintiffs for the putative class and appointed the firm Glancy, Prongay & Murray LLP lead counsel for the putative class. On February 14, 2019, the lead plaintiffs voluntarily dismissed the action, without prejudice, as to all defendants.

Edge and the Edge Board were named as defendants in two individual lawsuits and two putative class action lawsuits regarding the Merger, each of which alleged that the registration statement on Form S-4 (Registration No. 333-228937) filed by Edge on December 21, 2018 omitted material information with respect to the proposed transaction, which rendered the registration statement on Form S-4 false or misleading. The case captioned Michael Condon v. Edge Therapeutics et al., case no. 2:19-cv-00152 (the "Condon Action"), was filed on January 4, 2019 in the United States District Court for the District of New Jersey. The case captioned Adam Franchi et al. v. Edge Therapeutics et al., case no. 1:19-cv-00058-UNA (the "Franchi Action"), was filed on January 9, 2019 in the United States District Court for the District of Delaware. The case captioned Jeffrey L. Prince v. Edge Therapeutics et al., case no. 1:19-cv-00280 (the "Prince Action"), was filed on January 10, 2019 in the United States District Court for the Southern District of New York. The case captioned Brian Foldenauer et al. v. Edge Therapeutics et al., case no. 1:19-cv-00280 (the "Foldenauer Action"), was filed on January 22, 2019 in the United States District Court for the District of Delaware.

The causes of action set forth in each of the Condon Action, the Franchi Action, the Prince Action and the Foldenauer Action were (i) a claim against Edge and Edge's board of directors for violations of Section 14(a) of the Exchange Act, as well as (ii) a claim against Edge's board of directors for violations of Section 20(a) of the Exchange Act. In the Franchi Action, Private PDS was also named as a defendant in respect of the claim regarding violations of Section 20(a) of the Exchange Act. In each case, the plaintiffs sought, among other things, injunctive relief, rescissory damages, and an award of attorneys' fees and expenses.

On January 18, 2019, the plaintiffs in the Prince Action filed a motion for a preliminary injunction barring any stockholder vote on the Merger until revised disclosures was made to Edge's stockholders, and withdrew the motion for a preliminary injunction on February 1, 2019.

In March 2019, Edge (and Private PDS, with respect to the Franchi Action) settled each of the aforementioned actions in their entirety, and each case was voluntarily dismissed with prejudice, as follows: (i) the Franchi Action was dismissed on March 12, 2019; (ii) the Condon Action was dismissed on April 22, 2019; and (iii) the Prince Action and the Foldenauer Action were dismissed on March 14, 2019.

Retainer/Advisory and Finders' Fee Agreements

The Company entered into a consultant agreement with related party consultant (Related Party Consultant #1) described in Note 12, beginning in May 2016. Under the terms of the arrangement the Company will pay a 4.00% Finders' Fee of the aggregate gross proceeds received by the Company in any offering of Company securities from investors first introduced to the Company by related party consultant. The agreement was modified in September 2017 and the Finders' Fee owed was converted to common stock at $29.22 per share. In 2018, the Finders' Fee earned through December 2018 was converted to 3,001 shares at $15.33 per share. The agreement terminates in September 2021. No services were provided for the three months ended March 31, 2019

The Company entered into a 12 month agreement with a consultant (Consultant #1) beginning November 2017. Under the terms of the arrangement the Company will pay a monthly advisory fee of $5,000 to Consultant #1 for the first three months. In addition, the Company will pay a 4.00% Finders' Fee of the aggregate gross proceeds received by the Company in any offering of Company securities from investors first introduced to the Company by Consultant #1. As of October 31, 2018, no introductions had been made. The agreement terminated in November 2018.

The Company entered into a 12 month agreement with a consultant (Consultant #2) beginning November 2017. Under the terms of the arrangement the Company will pay a monthly consulting fee of $25,000 to Consultant #2 on the successful completion by the Company of not less than $1,000,000 in new equity funding during the term of the agreement. The Company will grant Consultant #2 a 5 year cashless option to purchase 0.5% of the Company's then outstanding common stock at a price equal to the price at which the Company conducts its next private offering of common stock and an additional five year cashless option to purchase 0.5% of the Company's then outstanding common stock at a price equal to the price at which the Company conducts its public offering of common stock, provided that such offering occurs within one year of the effective date. The Company issued Consultant #2 17,042 options to purchase common stock at $15.33 per share. The options were fully vested and expensed upon grant in 2018 and were issued outside of the 2018 Plan pool. The agreement terminated in October 2018.

The Company entered into a consultant agreement with related party consultant (Related Party Consultant #2) described in Note 13, beginning in December, 2017. Under the terms of the arrangement, the Company will pay a monthly consulting fee of 4,893 shares of common stock, which is equal to $75,000 based on the January 2018 price of $15.33 per share. The agreement was amended in July 2018. Under the terms of the amendment, the Company made a one-time payment to related party consultant of 14,676 shares at $15.33 per share in lieu of cash which equates to $225,000. The amendment also includes an opportunity for the consultant to be compensated with up to an additional 14,679 shares of the Company's common stock upon the achievement of certain future milestones and deliverables as defined with no current expiration date.

In February 2018, the Company entered into an agreement with a consultant (Consultant #3). Under the terms of the arrangement the Company will pay a monthly retainer of $7,000 to Consultant #3. In addition, if the Company retains a first financing, Consultant #3 will receive a one-time $15,000 bonus, and increase the retainer to $8,000 per month. Following the Company's merger transaction, the monthly retainer increased to $10,000 per month. The agreement can terminate any time with thirty days written notice.

Employment Matters

The Company has entered into employment agreements with each of its executive officers. The 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 three months ended March 31, 2019 and 2018, rent was $11,076 and $15,644, respectively, for arrangements not impacted by the adoption of ASC 842.

Note 12 – Related Party Transactions

In December 2014, a board member/investor (Board Member #1) signed a consulting agreement with the Company for $30,000 per year effective January 1, 2015. In July 2016, Board Member #1 converted balances outstanding of $45,000 into convertible promissory notes. The promissory notes plus related accrued interest totaling $46,042 were converted into equity in December 2016 resulting in the issuance of 1,969 shares of common stock at a price of $23.39 per share. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 Private Placement Memo ("PPM") and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 1,772 shares of common stock for the Board compensation convertible promissory note issued to Board Member #1 in 2016. For the nine months ended September 30, 2018, the Company incurred consulting fees of $22,500. Consulting fees outstanding to Board Member #1 at December 31, 2017 were $45,000. In October 2018, the Board agreed to grant Board Member #1 11,218 shares of common stock valued at $15.33 per share in lieu of cash compensation owed to date through the close of the Edge transaction predicted to close in March 2019. An additional $52,225 of consulting fees were expensed in 2018.

In December 2014, a board member/investor (Board Member #2) signed a consulting agreement with the Company for $15,000 per year effective January 1, 2015. In July 2016, the Board Member #2 converted balances outstanding of $22,500 into convertible promissory notes. The promissory notes plus related accrued interest totaling $23,020 were converted into equity in December 2016, resulting in the issuance of 984 shares of common stock at a price of $23.40 per share. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 PPM and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 886 shares of common stock for the Board compensation convertible promissory note issued to Board Member #2 in 2016. For the nine months ended September 30, 2018, the Company incurred consulting fees $11,250. Consulting fees outstanding to Board Member #2 at December 31, 2017 were $22,500. In October 2018, the Board agreed to grant Board Member #2 11,218 options to purchase common stock in lieu of cash compensation owed to date through the close of the Edge transaction predicted to close in March 2019. These options were granted immediately prior to the consummation of the Edge merger with an exercise price equal to $9.04. An additional estimated $69,100 of consulting fees were expensed in 2018. Once the exercise price was determined and the options were granted in March 2019, a reconciliation of a reversal of $13,781 of expense was booked. In November 2015, the Company received $1,000,000 from the Board Member #2 in exchange for a convertible promissory note. The promissory notes plus related accrued interest totaling $1,056,301 were converted into equity in December 2016, resulting in the issuance of 45,190 shares of common stock at a price of $23.38 per share. In December 2016, Board Member #2 purchased 8,556 shares of common stock in conjunction with a stock offering at a price of $29.22 per share, resulting in the receipt of $250,000 by the Company. In August 2016, the Company received $218,767 from Board Member #2 in exchange for a convertible promissory note. The promissory notes plus related accrued interest totaling $223,442 were converted into equity in December 2016, resulting in the issuance of 8,496 shares of common stock at a price of $26.30 per share. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 PPM and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 7,700, 40,671, and 7,647 shares of common stock, respectively for the December 2016 PPM, the November 2015 convertible promissory note, and the August 2016 convertible promissory note, respectively. In July 2018, Board Member #2 exercised 5,010 warrants at a price of $13.03 per share, resulting in the receipt of $65,277 by the Company. In August 2018, Board Member #2 exercised 2,662 warrants at a price of $13.03 per share, resulting in the receipt of $34,686 by the Company. In September 2018, Board Member #2 exercised 3,702 stock options at a price of $6.87 per share, resulting in the receipt of $25,406 by the Company. In October 2018, Board Member #2 exercised 13,946 stock options at a price of $6.87 per share, resulting in the receipt of $95,693 by the Company. In February 2019, Board Member #2 purchased 22,834 shares of common stock in conjunction with a stock offering at a price of $15.33 per share, resulting in the receipt of $350,000 by the Company. This investment also included 45% warrant coverage as well as anti-dilution protection resulting in additional issuance of 12,626 shares of common stock in March 2019.

In December 2014, a board member/investor (Board Member #3) signed a consulting agreement with the Company for $15,000 per year effective January 1, 2015. In July 2016, the Board Member #3 converted balances outstanding of $22,500 into convertible promissory notes. The promissory notes plus related accrued interest totaling $23,020 were converted into equity in December 2016, resulting in the issuance of 984 shares of common stock at a price of $23.40 per share. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 PPM and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 886 shares of common stock for the Board compensation convertible promissory note issued to Board Member #3 in 2016. For the nine months ended September 30, 2018, the Company incurred consulting fees $11,250. Consulting fees outstanding to Board Member #3 at December 31, 2017 were $22,500. In October 2018, the Board agreed to grant Board Member #3 11,218 options to purchase common stock in lieu of cash compensation owed to date through the close of the Edge transaction predicted to close in March 2019. These options were granted immediately prior to the consummation of the Edge merger with an exercise price equal to $9.04. An additional estimated $69,100 of consulting fees were expensed in 2018. Once the exercise price was determined and the options were granted in March 2019, a reconciliation of a reversal of $13,781 of expense was booked.

In May 2016, the Company received $500,000 from Board Member #4 in exchange for a convertible promissory note. The promissory notes plus related accrued interest totaling $516,096 were converted into equity in December 2016, resulting in the issuance of 22,079 shares of common stock at a price of $23.38 per share. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 PPM and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 19,871 shares of common stock for the May 2016 convertible promissory note. In October 2018, the Board agreed to grant a representative of Board Member #4 11,218 shares of common stock valued at $15.33 per share in lieu of cash compensation through the close of the Edge transaction predicted to close in March 2019. $85,975 of consulting fees were expensed in 2018. $85,975 remains in Prepaid Expenses as of December 31, 2018. The expense was amortized through March 2019.

In July 2016, the Company signed a consulting agreement with a related party (Related Party Consultant #1) to assist in raising capital. In addition, the consultant is entitled to a Finders' Fee of 4.00% of capital raised from its investors. In August 2016 the Company received $200,000 from Related Party Consultant #1 in exchange for a convertible promissory note. The promissory notes plus related accrued interest totaling $204,110 were converted into equity in December 2016, resulting in the issuance of 7,761 shares of common stock at a price of $26.30 per share. Finders' Fees of $46,000 and $93,400, were earned, respectively for December 31, 2018 and 2017. In lieu of cash payment, Related Party Consultant #1 elected to receive shares at the current fair value of $15.33 in 2018 and $29.22 in 2017 per common shares, resulting in the issuance of 3,001 and 3,196 common shares of the Company, respectively in 2018 and 2017. In January 2018, the Board of Directors approved the reduction in the price per common share listed in both the August 2016 PPM and December 2016 PPM from $29.22 to $15.33 per share. As a result, the Company issued an additional 6,985 and 2,876 shares of common stock, respectively, for the promissory note issued in 2016 and the Finders' Fee earned in 2017.

In December 2017, the Company signed a consulting agreement with a related party (Related Party Consultant #2) to provide marketing services. The Related Party Consultant #2 was entitled to a monthly consulting fee of $75,000. The agreement was amended in July 2018 and the consulting fee was reduced to $225,000 due to failure of Related Party Consultant #2 to produce new investors for the Company based on its marketing efforts. In lieu of the cash payment of $225,000, under the terms of the amendment, Related Party Consultant #2 elected to receive shares of common stock at the current fair value of $15.33 per common share, resulting in the issuance of 14,676 common shares of the Company.

Note 13 – Subsequent Events

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited interim condensed consolidated financial statements and related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report") and with the audited financial statements and notes thereto of Private PDS as of and for the year ended December 31, 2018 included in our Current Report on Form 8-K/A, filed with the Securities and Exchange Commission, or SEC, on April 30, 2019. As further described in "Note 1 – Nature of Operations" and "Note 3 – Reverse Merger" in this Quarterly Report, Private PDS was determined to be the accounting acquirer in the Merger and, accordingly, the pre-Merger historical financial information presented in this Quarterly Report reflects the standalone financial statements of Private PDS and, therefore, period-over-period comparisons may not be meaningful. Except as otherwise indicated herein or as the context otherwise requires, references in this Quarterly Report to "PDS" "the Company," "we," "us" and "our" refer to PDS Biotechnology Corporation, a Delaware corporation, on a post-Merger basis, and the term "Private PDS" refers to the business of privately held PDS Biotechnology Corporation prior to completion of the Merger.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly 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" below. 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 Quarterly Report and you should not place undue reliance on these forward-looking statements.

These forward-looking statements may 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 Quarterly Report reflect our views and assumptions only as of the date that this report is signed 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.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Overview

We are a clinical-stage biopharmaceutical company developing multi-dimensional cancer immunotherapies that are designed to overcome the limitations of the current approaches. PDS owns the Versamune®, T-cell activating platform, a proprietary multi-mechanism 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 2B and Phase 3 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-phase 2A clinical trial. The Phase 2A 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 additional preclinical studies, unique and rapid generation of a superior protective immune response has also been demonstrated by Versamune® in pandemic influenza strains.

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.

We acquired an in-process research and development, or IPR&D, asset relating to Edge's (as defined below) 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. We are currently seeking partners to continue the development of these product candidates and pursue them to commercialization.

We have never been profitable and have incurred net losses in each year since our inception, except for the three months ended March 31, 2019, during which we had net income of $6.8 million due to a bargain purchase gain of $11.7 million as a result of the Merger (as defined below). Our net losses were $2.9 million and $3.4 million for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, we had an accumulated deficit of $14.2 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 March 31, 2019, we had $26.6 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 discontinued Edge's prior business and acquired 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 3 – Reverse Merger" in the financial notes to our unaudited interim financial statements in Part I for more information on the Merger.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

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

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.

We acquired an in-process research and development, or IPR&D, asset relating to Edge's (as defined below) 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. We are currently seeking partners to continue the development of these product candidates and pursue them to commercialization.

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 tablet vaccine candidates.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes the results of our operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Increase (Decrease)	
	2019	2018	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 1,030	$ 201	$ 829	412%
General and administrative expenses	3,906	536	3,370	629%
Total operating expenses	4,936	737	4,199	570%
Loss from operations	(4,936)	(737)	(4,199)	570%
Other income (expense), net	11,730	–	11,730	100%
Interest income (expense), net	22	(1)	23	100%
Net loss and comprehensive loss	$ 6,816	$ (738)	$ 7,554	(1,024)%

Research and Development Expenses

Research and development (R&D) expenses increased to $1.0 million for the three months ended March 31, 2019 from $0.2 million for the three months ended March 31, 2018. The increase of $0.8 million in 2019 was primarily attributable to an increase in non-cash stock compensation expense of $0.4 million and an increase in $0.1 million in salaries. The increase is also due to an increase in $0.3 million in external expenses for clinical studies.

General and Administrative Expenses

General and administrative expenses increased to $3.9 million for the three months ended March 31, 2019 from $0.5 million for the three months ended March 31, 2018. The increase of $3.4 million is primarily attributable to an increase in non-cash stock compensation expense of $2.3 million and increase in bonuses of $0.4 million. In addition, there was an increase of $0.1 million in D&O insurance and an increase of $0.1 million of outside professional consulting fees plus $0.4 million in legal fees.

Other income (expense), net

Other income, net was $11.7 million during the three months ended March 31, 2019, an increase of $11.7 million as compared to other income of $0 during the three months ended March 31, 2018, due to a bargain purchase gain 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.

Interest income (expense), net

Interest income, net was $0.02 million during the three months ended March 31, 2019, an increase of $0.03 million, as compared to an expense of $(0.01) million during the three months ended March 31, 2018, due to interest received on invested cash.

Liquidity and Capital Resources

Since inception, our operations have been financed primarily by net proceeds of $12.3 million from the sale of our common stock and $5.4 million from the issuance of convertible promissory notes. As of March 31, 2019, we had $26.6 million of cash and cash equivalents, including $29.1 million of pre-existing cash on Edge's balance sheets that we obtained as a result of the Merger. 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 plan to continue to fund our operations and capital funding needs through equity and/or debt financings. 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.

Cash Flows

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

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (3,367)	$ (404)
Net cash provided by investing activities	29,106	–
Net cash provided by financing activities	750	1,052
Net increase in cash	$ 26,489	$ 648

Net Cash Used in Operating Activities

Net cash used in operating activities was $3.4.million and $0.4 million for the three months ended March 31, 2019 and 2018, respectively. The increase in cash used in operating activities of $3.0 million was primarily due to the increase of operating activities and payment of the Merger restructuring costs as compared to the prior year.

Net Cash Used in Investing Activities

Net cash used in investing activities in 2019 relates entirely to cash received in the Merger.

Net Cash (Used In) Provided by Financing Activities

Net cash used in financing activities for the three months ended March 31, 2019 was due to the receipt of net proceeds from exercise of stock options of $0.8 million.

Net cash provided by financing activities for the three months ended March 31, 2018 was due to the receipt of net proceeds of $1.1 million due to 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.

We believe that our existing cash and cash equivalents as of March 31, 2019 will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this Quarterly 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 the Quarterly 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 March 31, 2019	Total	Less than one year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations	$ 1,585	$ 602	$ 983	$ –	$ –
Milestone payments	100	100	–	–	–
Total contractual obligations	$ 1,685	$ 702	$ 983	$ –	$ –

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.

Critical Accounting Polices 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 financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We consider our critical accounting policies and estimates to be related to stock-based compensation and IPR&D. There have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2019 from those disclosed in our audited financial statements for the year ended December 31, 2018, which we filed with the Securities and Exchange Commission in our Current Report on Form 8-K/A on April 30, 2019.

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 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The primary objectives of our investment activities are to ensure liquidity and to preserve principal, while at the same time maximizing the income we receive from our cash and marketable securities without significantly increasing risk. As of March 31, 2019, we had cash equivalents of $26.6 million that were held in a non-interest-bearing money operating account and an institutional U.S. Treasury money market fund. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, we do not believe that an immediate 100 basis point change in interest rates would have a material effect on the fair market value of our cash equivalents. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are comprised of U.S. Treasury and Treasury backed repurchase agreements.

ITEM 4: 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 Securities Exchange Act of 1934, or the Exchange Act, as of the end of the period covered by this report. Based on such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are 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.

Changes in Internal Control over Financial Reporting

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 throughout calendar year 2019. Edge Therapeutics was previously subject to the provisions of the Sarbanes-Oxley Act of 2002, as amended ("SOX"), whereas PDS Biotechnology Corporation, which prior to the Merger was a private, non-reporting operating company was not. The 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 covered by this report.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

On April 23, 2018, a purported securities class action complaint was filed against Edge, Brian Leuthner (Edge's President and Chief Executive Officer) and Andrew Saik (Edge's Chief Financial Officer and our current Chief Financial Officer) in the United States District Court for the District of New Jersey, captioned *Sanfilippo v. Edge Therapeutics, Inc.*, Case No. 2:18-cv-8236. The complaint alleged that Edge, Mr. Leuthner and Mr. Saik violated Section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements concerning Edge's business, operations and prospects by failing to disclose that EG-1962 would likely fail a futility analysis. The complaint also asserted a "control" person claim against Mr. Leuthner and Mr. Saik pursuant to Section 20(a) of the Exchange Act. The complaint was brought on behalf of all purchasers of Edge's common stock between December 27, 2017 and March 27, 2018, and sought unspecified damages. On December 7, 2018, the court appointed Sam Kirkpatrick and Amos Bakouple lead plaintiffs for the putative class and appointed the firm Glancy, Prongay & Murray LLP lead counsel for the putative class. On February 14, 2019, the lead plaintiffs voluntarily dismissed the action, without prejudice, as to all defendants.

Edge and the Edge Board were named as defendants in two individual lawsuits and two putative class action lawsuits regarding the Merger, each of which alleged that the registration statement on Form S-4 (Registration No. 333-228937) filed by Edge on December 21, 2018 omitted material information with respect to the proposed transaction, which rendered the registration statement on Form S-4 false or misleading. The case captioned Michael Condon v. Edge Therapeutics et al., case no. 2:19-cv-00152, or the Condon Action, was filed on January 4, 2019 in the United States District Court for the District of New Jersey. The case captioned Adam Franchi et al. v. Edge Therapeutics et al., case no. 1:19-cv-00058-UNA, or the Franchi Action, was filed on January 9, 2019 in the United States District Court for the District of Delaware. The case captioned Jeffrey L. Prince v. Edge Therapeutics et al., case no. 1:19-cv-00280, or the Prince Action, was filed on January 10, 2019 in the United States District Court for the Southern District of New York. The case captioned Brian Foldenauer et al. v. Edge Therapeutics et al., case no. 1:19-cv-00280, or the Foldenauer Action, was filed on January 22, 2019 in the United States District Court for the District of Delaware.

The causes of action set forth in each of the Condon Action, the Franchi Action, the Prince Action and the Foldenauer Action were (i) a claim against Edge and Edge's board of directors for violations of Section 14(a) of the Exchange Act, as well as (ii) a claim against Edge's board of directors for violations of Section 20(a) of the Exchange Act. In the Franchi Action, Private PDS was also named as a defendant in respect of the claim regarding violations of Section 20(a) of the Exchange Act. In each case, the plaintiffs sought, among other things, injunctive relief, rescissory damages, and an award of attorneys' fees and expenses.

On January 18, 2019, the plaintiffs in the Prince Action filed a motion for a preliminary injunction barring any stockholder vote on the Merger until revised disclosures was made to Edge's stockholders, and withdrew the motion for a preliminary injunction on February 1, 2019.

In March 2019, Edge (and Private PDS, with respect to the Franchi Action) settled each of the aforementioned actions in their entirety, and each case was voluntarily dismissed with prejudice, as follows: (i) the Franchi Action was dismissed on March 12, 2019; (ii) the Condon Action was dismissed on April 22, 2019; and (iii) the Prince Action and the Foldenauer Action were dismissed on March 14, 2019.

ITEM 1A. RISK FACTORS

Any investment in our business involves a high degree of risk. Before making an investment decision, you should carefully consider the information we include in this Quarterly Report on Form 10-Q, including our unaudited interim condensed consolidated financial statements and accompanying notes, and the additional information in the other reports we file with the Securities and Exchange Commission. These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline and you could lose part or all of your investment. Set forth below are certain risk factors applicable to our business that we believe are important to highlight.

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 March 31, 2019, we had an accumulated deficit of $14.2 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.

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, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. 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.

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 March 31, 2019, we had 10 employees and 5 consultants. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. 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 (HIPAA) and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which goes 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. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and 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 may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it 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.

The recently enacted tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or TCJA, which significantly amends the Internal Revenue Code of 1986. The TCJA, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted earnings, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the effect these changes may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected.

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 or clinical trial protocols with prospective trial sites;
- 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.

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 GCP 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 markets PDS0101 for indications other than its approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs 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 approval that we may have obtained.

Even if PDS0101 receives marketing approval, 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 state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, 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. The laws that may affect our ability to operate include, but are not limited to:

- the Federal Anti-Kickback Statute, 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 Federal Anti-Kickback Statute, 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 FCA'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;

- the FCA'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;

- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal beneficiary inducement statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;

- the federal physician sunshine 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; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. 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. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, it could face action against it 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 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 legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize PDS0101 and affect the prices we may obtain.

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.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. 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.

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 partes 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 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 March 31, 2019, we had 5,172,938 shares of common stock outstanding. Approximately 3,320,000 of such shares are freely tradable, without restriction, in the public market. Approximately 1,846,000 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 29.% of the outstanding shares of our common stock as of March 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 $148 million and $29.5 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 expects 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.

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. We are currently and in the future 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Sales of Unregistered Securities

There were no unregistered sales of the Company's equity securities during the quarter ended March 31, 2019.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits filed with this Quarterly Report or incorporated herein by reference is set forth in the Exhibit Index immediately preceding the signature page of this report and is incorporated into this Item 6 by reference.

EXHIBIT INDEX

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).
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 Eighth Amended and Restated Certificate of Incorporation for Corporate Name Change (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 18, 2019, and incorporated by reference herein).
3.4	Certificate of Amendment to Eighth Amended and Restated Certificate of Incorporation for Reverse Stock Split (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on March 18, 2019, and incorporated by reference herein).
10.1	Letter Agreement, dated as of 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).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1 *	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2 *	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
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

* The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PDS Biotechnology Corporation

May 14, 2019 By: /s/ Frank Bedu-Addo
Frank Bedu-Addo
President and Chief Executive Officer
(Principal Executive Officer)

May 14, 2019 By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Frank Bedu-Addo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PDS Biotechnology Corporation for the period ended March 31, 2019;

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

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

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

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

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

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

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

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

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

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

Dated: May 14, 2019

/s/ Frank Bedu-Addo
Frank Bedu-Addo
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Saik, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PDS Biotechnology Corporation for the period ended March 31, 2019;

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

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

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

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

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

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

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

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

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

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

Dated: May 14, 2019

/s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report of PDS Biotechnology Corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2019 (the "Report"), I, Frank Bedu-Addo, President and Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 14, 2019

/s/ Frank Bedu-Addo
Frank Bedu-Addo
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Quarterly Report of PDS Biotechnology Corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2019 (the "Report"), I, Andrew Saik, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 14, 2019

/s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)