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 September 30, 2019

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

For the transition period from_____to_____

Commission file number 001-37568

PDS Biotechnology Corporation

(Exact name of registrant as specified in its charter)

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

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

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

(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 October 31, 2019 was 5,778,850.

PDS BIOTECHNOLOGY CORPORATION

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 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 three and nine months period endedSeptember 30, 2019, which includes the date of the completion of the Merger, and is therefore the Company's third 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

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,406,608	$ 103,695
Prepaid expenses and other	726,959	156,628
Total current assets	18,133,567	260,323
Property and equipment, net	26,929	29,508
Intangible assets, net	1,223,000	41,692
Other assets	–	12,800
Total assets	$ 19,383,496	$ 344,323
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,488,961	$ 1,412,951
Accrued expenses	1,296,606	601,889
Restructuring reserve	858,332	–
Total current liabilities	3,643,899	2,014,840
Noncurrent liability:		
Deferred tax liability	157,000	–
Convertible promissory notes payable	–	30,000
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, 5,000,000 shares authorized at September 30, 2019 and December 31, 2018, 0 outstanding	–	–
Common stock, $0.00033 par value, 75,000,000 shares authorized at September 30, 2019 and December 31, 2018, 5,278,850 shares and 3,417,187 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	1,742	1,128
Additional paid-in capital	39,414,792	19,311,529
Accumulated deficit	(23,833,937)	(21,013,174)
Total stockholders' equity (deficit)	15,582,597	(1,700,517)
Total liabilities and stockholders' equity (deficit)	$ 19,383,496	$ 344,323

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development expenses	$ 1,834,371	$ 194,068	$ 4,751,308	$ 563,812
General and administrative expenses	3,068,581	516,202	9,358,429	1,450,429
Lease termination costs	944,445	–	944,445	–
Total operating expenses	5,847,397	710,270	15,054,182	2,014,241
Loss from operations	(5,847,397)	(710,270)	(15,054,182)	(2,014,241)
Other income (expense):				
Gain on bargain purchase upon merger	–	–	11,939,331	–
Interest income	95,787	4	294,694	14
Interest expense	–	(942)	(606)	(2,705)
Net loss and comprehensive loss	(5,751,610)	(711,208)	(2,820,763)	(2,016,932)
Net loss per share, basic and diluted	$ (1.10)	$ (0.21)	$ (0.60)	$ (0.62)
Weighted average common shares outstanding, basic and diluted	5,246,829	3,346,237	4,729,153	3,253,085

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	Accumulated	Total
	Shares Issued	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance - June 30, 2018	3,341,143	$ 1,103	$ 18,599,631	$ (19,408,342)	$ (807,608)
Stock-based compensation expense	–	–	41,691	–	41,691
Capitalized offering costs	–	–	(2,000)	–	(2,000)
Issuance of common stock, net of issuance costs	17,942	6	274,994	–	275,000
Issuance of common stock for warrant exercise	7,673	3	99,960	–	99,963
Issuance of common stock for stock option exercise	3,702	2	25,405	–	25,407
Net loss	–	–	–	(711,208)	(711,208)
Balance - September 30, 2018	3,370,460	$ 1,114	$ 19,039,681	$ (20,119,550)	$ (1,078,755)

	Common Stock		Additional	Accumulated	Total
	Shares Issued	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance - June 30, 2019	5,177,487	$ 1,709	$ 38,686,233	$ (18,082,327)	$ 20,605,615
Stock-based compensation expense	–	–	120,207	–	120,207
Issuance of common stock from 401K match	709	–	4,461	–	4,461
Issuance of common stock from equity transaction	100,654	33	603,891	–	603,924
Net loss	–	–	–	(5,751,610)	(5,751,610)
Balance - September 30, 2019	5,278,850	$ 1,742	$ 39,414,792	$ (23,833,937)	$ 15,582,597

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	Accumulated	Total
	Shares Issued	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance - December 31, 2017	3,051,538	$ 1,007	$ 17,492,083	$ (18,102,618)	$ (609,528)
Stock-based compensation expense	–	–	49,336	–	49,336
Capitalized offering costs	–	–	(46,000)	–	(46,000)
Issuance of common stock, net of issuance costs	307,547	102	1,076,792	–	1,076,894
Issuance of common stock for warrant exercise	7,673	3	99,960	–	99,963
Issuance of common stock for stock option exercise	3,702	2	25,405	–	25,407
Issuance of warrants	–	–	342,105	–	342,105
Net loss	–	–	–	(2,016,932)	(2,016,932)
Balance - September 30, 2018	3,370,460	$ 1,114	$ 19,039,681	$ (20,119,550)	$ (1,078,755)

	Common Stock		Additional	Accumulated	Total
	Shares Issued	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance - December 31, 2018	3,417,187	$ 1,128	$ 19,311,529	$ (21,013,174)	$ (1,700,517)
Stock-based compensation expense	–	–	2,893,658	–	2,893,658
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
Issuance of common stock from 401K match	5,258	2	29,702	–	29,704
Issuance of common stock from equity transaction	100,654	33	603,891	–	603,924
Equity from merger transaction	1,599,178	528	15,793,110	–	15,793,638
Net loss	–	–	–	(2,820,763)	(2,820,763)
Balance - September 30, 2019	5,278,850	$ 1,742	$ 39,414,792	$ (23,833,937)	$ 15,582,597

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (2,820,763)	$ (2,016,932)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,893,658	49,336
Stock-based consulting expense	603,924	268,999
Stock-based 401K company common match	29,705	–
Depreciation expense	93,814	21,415
Loss on disposal of fixed assets related to lease termination	310,951	–
Bargain purchase gain from merger	(11,939,331)	–
Changes in assets and liabilities:		
Prepaid expenses and other assets	1,908,520	34,366
Accounts payable	(1,521,516)	244,305
Accrued expenses	(900,622)	146,562
Restructuring reserve	(1,211,939)	–
Net cash used in operating activities	(12,553,599)	(1,251,949)
Cash flows from investing activities:		
Cash received in reverse merger transaction	29,106,512	–
Net cash provided by investing activities	29,106,512	–
Cash flows from financing activities:		
Payments for capital lease obligation	–	(10,636)
Proceeds from issuance of common stock, net of issuance costs	750,000	1,229,370
Net cash provided by financing activities	750,000	1,218,734
Net increase (decrease) in cash and cash equivalents	17,302,913	(33,215)
Cash and cash equivalents at beginning of period	103,695	175,884
Cash and cash equivalents at end of period	$ 17,406,608	$ 142,669
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ 606	$ 1,022
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 cancer at various stages, including head and neck cancer, prostate cancer, breast cancer, cervical cancer, anal cancer, and other cancers. All of PDS's products are based on the proprietary Versamune® platform technology, which activates and directs the human immune system to unleash a powerful and targeted attack against cancer cells. The Versamune®-based immunotherapies may be used as monotherapies or in combination with other agents. PDS is initially prioritizing the development of the Versamune®-based products as combination therapies to be administered with other potentially synergistic agents such as FDA-approved therapeutic or immunotherapeutic agents and promising therapeutic agents still in clinical development.

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

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

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 September 30, 2019, the statements of operations and comprehensive loss and changes in stockholders' equity (deficit) for the three and nine months ended September 30, 2019 and 2018, and cash flows for the nine months ended September 30, 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 and nine months ended September 30, 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 clinical and regulatory development of its products, 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) Intellectual property:

PDS strives to protect and enhance the proprietary technology, inventions and improvements that are commercially important to its business, including seeking, maintaining, and defending patent rights. PDS has developed numerous patents and patent applications related to its Versamune® platform. As of September 30, 2019, PDS holds four (4) U.S. patents with granted claims directed to its platform technology and six (6) pending patent applications. These issued patents will expire in 2025, 2031, 2031 and 2033, respectively. Should the more recently submitted patents currently in prosecution be issued, these will expire in 2033 through 2037 assuming no patent term extensions are granted. As of September 30, 2019, PDS holds twenty (22) issued foreign patents and thirty-three (33) pending foreign patent application which cover compositions of matter and methods of use related to its platform technology. These issued patents will expire in 2031-2034, or later if patent term extension applies.

Licensed patents

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

(H) Intangibles:

The Company's intangible assets as of September 30, 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 will next test its IPR&D on December 1, 2019. The Company's IPR&D asset totaled $1.2 million at September 30, 2019.

There were no trigger events during the three months and nine months ended September 30, 2019 to which an impairment analysis would be warranted.

(I) 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 stock-based 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.

(J) 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.

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.

In February 2019, the Company issued 48,930 shares of common stock for proceeds of $750,000. In exchange for the financing, 34,192 of warrants were issued with an exercise price of $9.87 and an expiration date of December 31, 2023.

(K) 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 September 30, 2019 and as of September 30, 2018 have 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 September 30,	
	2019	2018
Stock options to purchase Common Stock	1,405,902	513,534
Convertible promissory note	-	9,216
Warrants to purchase Common Stock	262,758	115,860
Total	1,668,660	638,610

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator				
Basic and diluted net loss	$ (5,751,610)	$ (711,208)	$ (2,820,763)	$ (2,016,932)
Denominator				
Shares used in computing basic net loss per share	5,246,829	3,346,237	4,729,153	3,253,085
Net loss per share, basic and diluted	$ (1.10)	$ (0.21)	$ (0.60)	$ (0.62)

(L) 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.

(M) Accounting standards adopted:

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The Company adopted the new lease standard, as of January 1, 2019, using the optional transition method under which comparative financial information will not be restated and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease; did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. Furthermore, the Company did not have any leases impacted by ASC 842 on the adoption date. As part of the purchase price allocation from the reverse merger, the Company recorded a Right of Use asset and Liability of $1.4 million. See Note 7 for update.

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 – Liquidity

As of September 30, 2019, the Company had $17.4 million of cash and cash equivalents, primarily provided by $29.1 million of pre-existing cash on Edge's balance sheets that the Company obtained as a result of the Merger. The Company's primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when the Company pays these expenses, as reflected in the change to the Company's outstanding accounts payable and accrued expenses.

On July 29, 2019, the Company entered into a common stock purchase agreement (the "Aspire Purchase Agreement") pursuant to which, the Company has the right, in its sole discretion, to present Aspire Capital Fund, LLC ("Aspire Capital") with a purchase notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of the Company's common stock per business day, in an aggregate amount of up to $20.0 million of the Company's common stock (the "Purchase Shares") over the term of the Aspire Purchase Agreement at a per share price equal to the lesser of the lowest sale price of the Company's common stock on the purchase date or the arithmetic average of the three lowest closing sale prices for the Company's common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date. The Company may sell an aggregate of 1,034,979 shares of its common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. The Company may sell additional shares of its common stock above the 19.99% limit provided that (i) it obtains stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of the Company's common stock on July 26, 2019. The minimum price at which the Company sell shares under the Aspire Purchase Agreement is $0.50. On July 29, 2019, the Company issued 100,654 shares of common stock to Aspire Capital as consideration for entering into the Aspire Purchase Agreement . The Company recorded the fair value of the shares at July 29, 2019 of $603,924 as an expense in the third quarter of 2019. The Company has not issued any shares of its common stock to Aspire Capital under the Aspire Purchase Agreement, aside from the 100,654 shares that were issued to Aspire Capital as consideration for entering into the Aspire Purchase Agreement (the "Commitment Shares"). Concurrently with the Aspire Purchase Agreement, the Company entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"). In accordance with the Registration Rights Agreement, on August 20, 2019 the Company filed a Registration Statement on Form S-1(File No. 333-232988) to cover the resale of the Commitment Shares and any Purchased Shares issuable to Aspire Capital under the Aspire Purchase Agreement. There is market uncertainty regarding the utilization of financing associated from the Aspire Purchase Agreement. As of September 30, 2019, no Purchase Shares were sold to Aspire Capital under the Aspire Purchase Agreement.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q. Based on such evaluation and the Company's current plans, which are subject to change, management believes that the Company's existing cash and cash equivalents as of September 30, 2019 and proceeds expected to become available through government funding programs will be sufficient to satisfy its operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q.

The Company plans to continue to fund the Company's operations and capital funding needs through equity and/or debt financings. The Company may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to the Company's stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict the Company's operations. If the Company's was unable to raise additional capital in sufficient amounts or on acceptable terms, the Company may be required to delay, limit, reduce, or terminate the Company's product development or future commercialization efforts or grant rights to develop and market immunotherapies that the Company would otherwise prefer to develop and market ourselves. Any of these actions could harm the Company's business, results of operations and prospects.

Note 4 – Reverse Merger

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

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

For accounting purposes, Private PDS is considered to be the accounting acquirer in the Merger because Private PDS's stockholders owned approximately 70% of the combined company's common stock immediately following the closing of the Merger. As the accounting acquirer, Private PDS's assets and liabilities continue to be recorded at their historical carrying amounts and the historical operations that will be reflected in the Company's 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. During the three months ended June 30, 2019, two adjustments were made to the preliminary valuation. The first was for $275,000 relating to an offer to purchase equipment that was given a valuation of $0 on the date of acquisition. The second was for $65,551 relating to Edge's bonus plan that was effective prior to the date of acquisition. 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. 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)	1,716,732
Right to use asset	1,384,810
Intangible assets-IPR&D	1,223,000
Total identifiable assets acquired	33,431,055
Accounts payable, accrued expenses, other liabilities	(4,595,934)
Lease liability	(945,152)
Deferred tax liability	(157,000)
Total liabilities assumed	(5,698,086)
Net identifiable assets acquired	27,732,969
Bargain purchase gain	(11,939,331)
Purchase price	$ 15,793,638

(1) The valuation of equipment held for sale was believed to be $0 at the date of acquisition based on recent sales interest. Subsequent to the acquisition date, there was an offer on the equipment for a price of $275,000, as such the Company deemed this would have been the value of the equipment if this sales offer would been available at the date of acquisition.

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 September 30, 2019 and 2018 assume the Merger was completed as of January 1, 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Pro forma operating expenses	$ 15,964,969	$ 5,162,697	$ 25,171,754	$ 39,067,927
Pro forma net loss	(16,552,729)	(4,976,379)	(13,621,882)	(39,799,838)
Pro forma basic and diluted net loss per share	$ (3.15)	$ (1.01)	$ (2.88)	$ (8.28)

The September 30, 2019 pro forma net loss excludes the bargain purchase gain that resulted from the Merger.

Note 5 – Fair Value of Financial Instruments

There were no transfers 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 September 30, 2019: (unaudited)				
Cash and cash equivalents	$ 17,406,608	$ 17,406,608	$ –	$ –
As of December 31, 2018:				
Cash and cash equivalents	$ 103,695	$ 103,695	$ –	$ –

Note 6 – Intangible Assets

As of September 30, 2019, $1,223,000 was for IPR&D resulting from the Merger's preliminary purchase price allocation. This asset is not amortized. See Note 4.

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 7 – Leases

The Company adopted Accounting Standards Codification (ASC) Topic 842 on the date of the Merger and recognized an operating right-of-use (ROU) asset of $1.4 million and operating lease liabilities of $1.4 million at upon acquiring the lease in the reverse merger. The Company leases office space in Berkeley Heights, New Jersey that was expected to expire on November 15, 2021 under an operating lease. The Company has the option to renew the lease for five years. The Company evaluated the renewal option at the lease commencement date and determined that it will not excise the option to renew. 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 availableon the date of the Merger. The discount rate used to measure the operating lease liability as of September 30, 2019 was 10.15%.

For the three and nine months ended September 30, 2019, the Company’s operating lease expense was $98,648 and $271,283 respectively.

On July 8, 2019, the Company entered into a lease termination agreement for its office space located at 300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922 effective August 31, 2019 (the “Lease Termination Agreement”). Pursuant to the Lease Termination Agreement, the Company is required to pay 50 percent of the remaining lease payments of $665,802 over three installments on September 1, 2019, December 1, 2019, and March 1, 2020, which was recorded as lease termination costs. The Company maintains a month-to-month lease for its research facilities at the Princeton Innovation Center BioLabs located at 303A College Road E, Princeton NJ 08540. The Company entered into a temporary month-to-month lease as of September 1, 2019 for office space located at 830 Morris Turnpike, Short Hills NJ 07078 until the Company enters into a new lease for permanent office space. On August 31, 2019, the right-of-use asset of $1.2 million and operating lease liability of $1.2 million was written off. Leasehold improvements amounting to approximately $0.3 million were also written off and are included in lease termination costs.

Note 8 – Accrued Expenses and Restructuring Reserve

Accrued expenses and other liabilities consist of the following:

	As of September 30, 2019	As of December 31, 2018
Accrued research and development costs	$ 132,538	$ 71,329
Accrued professional fees	230,337	421,617
Accrued compensation	489,863	54,269
Accrued other	–	46,674
Accrued rent termination	443,868	8,000
Total	$ 1,296,606	$ 601,889

Restructuring Reserve

	As of September 30, 2019	As of December 31, 2018
Restructuring reserve (1)	$ 858,332	$ –
Total	$ 858,332	$ –

(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. The severance costs continue through September 2020. For the nine months ended September 30, 2019, the Company paid $1,211,939 of restructuring expense which was previously recorded on Edge Therapeutics financials.

Note 9 – Convertible Promissory Note

In November 2017, the Company received $30,000 from an investor in exchange for a convertible promissory note bearing interest at 7.50% per annum.

The original terms of the promissory note was amended in December 2018 and states that in the event the Company consummates a sale of the Company prior to the conversion or repayment in full of this Note, the outstanding principal amount and all accrued but unpaid interest due shall automatically convert into the numbers of shares of the Company's common stock equal to (a) the principal amount plus all accrued but unpaid interest thereon, divided by (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 10 – 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.

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

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

The Company’s stock-based compensation expense related to stock options was recognized in operating expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Stock-Based Compensation				
Research and development	$ 49,748	$ 21,582	$ 499,835	$ 24,801
General and administrative	70,458	20,109	2,393,823	24,535
Total	$ 120,206	$ 41,691	$ 2,893,658	$ 49,336

The fair value of options granted during the three and nine months ended September 30, 2019 and 2018 was estimated using the Black-Scholes option valuation model utilizing the following assumptions. For the three and nine months ended September 30, 2018, the Company granted a total of 95,300 options on July 6, 2018.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
	(unaudited)		(unaudited)	
Volatility	92.22%	83.60%	89.88%	83.60%
Risk-Free Interest Rate	1.49%	2.75%	2.33%	2.75%
Expected Term in Years	6.08	6.25	6.14	6.25
Dividend Rate	0.00%	0.00%	0.00%	0.00%
Fair Value of Option on Grant Date	$ 3.50	$ 12.91	$ 5.30	$ 12.91

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	806,137	7.55		
Exercised	–	–		
Forfeited	(289,049)	97.80		
Options outstanding at September 30, 2019	1,405,902	$ 17.05	7.20	$ –
Vested and expected to vest at September 30, 2019	1,405,902	$ 17.05	7.20	$ –
Exercisable at September 30, 2019	1,006,972	$ 21.37	6.19	$ –

At September 30, 2019 there was approximately $1,753,155 of unamortized stock option compensation expense, which is expected to be recognized over a remaining average vesting period of 3.61 years. See Note 3 for stock based compensation related to Aspire commitment share issuance.

Note 11 – 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 September 30, 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 and nine months ended September 30, 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 September 30, 2019, 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 and nine months ended September 30, 2019 and for the year ended December 31, 2018.

Note 12 – Commitments and Contingencies

Retainer/Advisory and Finders' Fee Agreements

The Company entered into several consultant agreements beginning in May 2016 for retainer fees, advisory fees and finders' fees. The fees were settled either with cash or issuance of common stock. Expenses recorded for the three and nine months period ended September 30, 2018 were $181,500 and $299,000 respectively. There were no fees paid in the three and nine months period ended September 30, 2019.

Employment Matters

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

Rent

For the three and nine months ended September 30, 2019 and 2018, rent was $38,365 and $58,665 and $15,644 and $46,931, respectively for month-to-month arrangements not impacted by the adoption of ASC 842.

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 as part of combination therapies with other leading immuno-oncology technologies. We expect substantial value accretion as its development-stage products successfully progress through upcoming human Phase 2 clinical trials.

The unique combination of high potency and excellent safety of the Versamune® platform observed in preclinical studies appears to be corroborated in a successfully completed 12-patient Phase 1/2a clinical trial. The Phase 1 human trial immune responses mirrored the strong reported T-cell responses seen in preclinical studies, which led to superior anti-tumor regression efficacy in pre-clinical head-to-head studies with leading clinical development-stage technologies. Superior anti-tumor response of PDS0101 monotherapy versus combinations of top competitors e.g. cancer vaccines + checkpoint inhibitors or chemotherapy was also demonstrated in preclinical studies. On September 19, 2019, PDS reported retrospective clinical outcome data from this study. The study demonstrated robust treatment-induced HPV16-specific killer T-cell (CD8+) responses as well as regression of lesions in 60% of evaluable patients. In additional preclinical studies, unique and rapid generation of a superior protective immune response has also been demonstrated by Versamune® in pandemic influenza strains.

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

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

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

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. Our net losses were $2.9 million and $3.4 million for the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019, we had an accumulated deficit of $23.8 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 September 30, 2019, we had $17.4 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 September 30, 2019 and 2018

The following table summarizes the results of our operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase (Decrease)	
	2019	2018	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 1,835	$ 194	$ 1,641	846%
General and administrative expenses	3,069	516	2,553	495%
Lease termination costs	944	–	944	100%
Total operating expenses	5,848	710	5,138	724%
Loss from operations	(5,848)	(710)	(5,138)	724%
Interest income (expense), net	96	(1)	97	9,700%
Net loss and comprehensive loss	$ (5,752)	$ (711)	$ (5,041)	709%

Research and Development Expenses

Research and development (R&D) expenses increased to $1.8 million for the three months ended September 30, 2019 from $0.2 million for the three months ended September 30, 2018. The increase of $1.6 million in 2019 was primarily attributable to an increase in external expenses for clinical studies of $1.1 million and an increase of $0.5 million in personnel costs.

General and Administrative Expenses

General and administrative expenses increased to $3.1 million for the three months ended September 30, 2019 from $0.5 million for the three months ended September 30, 2018. The increase of $2.6 million is primarily attributable to increases in personnel costs of $0.5 million, $0.5 million in D&O insurance, $0.6 for stock based consulting fees, $0.2 million for professional fees, $0.4 million in legal fees and $0.4 in other operating expenses.

Lease Termination Costs

The lease termination costs relates to moving the Company's corporate offices and consists of $0.6 million for lease termination fees and $0.3 million for disposal of leasehold improvements and office furniture.

Interest income (expense), net

Interest income, net was $0.1 million during the three months ended September 30, 2019, an increase of $0.1 million, as compared to an expense of $(0.01) million during the three months ended September 30, 2018, due primarily to interest received on invested cash and cash equivalents.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase (Decrease)	
	2019	2018	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 4,752	$ 564	$ 4,188	743%
General and administrative expenses	9,359	1,450	7,909	545%
Lease termination costs	944	-	944	100%
Total operating expenses	15,055	2,014	13,041	648%
Loss from operations	(15,055)	(2,014)	(13,041)	648%
Other income (expense), net	11,939	–	11,939	100%
Interest (expense), net	295	(3)	298	(9,933)%
Net loss and comprehensive loss	$ (2,821)	$ (2,017)	$ (804)	40%

Research and Development Expenses

Research and development (R&D) expenses increased to $4.8 million for the nine months ended September 30, 2019 from $0.6 million for the same period in 2018. The increase of $4.2 million was primarily attributable to an increase in external expenses for clinical studies of $2.8 million and internal R&D personnel costs of $0.8 million, non-cash stock based compensation of $0.5 million and departmental costs of $0.1 million.

General and Administrative Expenses

General and administrative expenses increased to $9.4 million for the nine months ended September 30, 2019 from $1.5 million for the same period in 2018. The $7.9 million increase was due to increases in personnel costs of $1.4 million, non-cash stock based compensation of $2.4 million, $0.6 for stock based consulting fees, facilities costs of $0.3 million, D&O insurance costs of $1.0 million, legal fees of $1.1 million, professional fees of $0.5 million and $0.6 million in other operating expenses.

Lease Termination Costs

The lease termination costs relates to moving the Company's corporate offices and consists of $0.6 million for lease termination fees and $0.3 million for disposal of leasehold improvements and office furniture.

Other income (expense), net

Other income, net was $11.9 million during the nine months ended September 30, 2019, an increase of $11.9 million as compared to other income of $0 during the nine months ended September 30, 2018, due to the 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 $0.3 million during the nine months ended September 30, 2019, an increase of $0.3 million during the nine months ended September 30, 2018, due primarily to interest received on invested cash and cash equivalents.

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 September 30, 2019, we had $17.4 million of cash and cash equivalents, primarily derived from the $29.1 million of pre-existing cash on Edge's balance sheets that we obtained as a result of the Merger. Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q. Based on such evaluation and our current plans, which are subject to change, management believes that our existing cash and cash equivalents as of September 30, 2019 and proceeds expected to become available through government funding programs will be sufficient to satisfy our operating cash needs for at least one year after the filing of this Quarterly Report on Form 10-Q.

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.

On July 29, 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, pursuant to which, we have the right, in our sole discretion, to present Aspire Capital Fund, LLC, or Aspire Capital, with a purchase notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, in an aggregate amount of up to $20.0 million of our common stock, or the Purchased Shares, over the term of the Aspire Purchase Agreement at a per share price equal to the lesser of the lowest sale price of our common stock on the purchase date or the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date. We may sell an aggregate of 1,034,979 shares of our common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. We may sell additional shares of our common stock above the 19.99% limit provided that (i) we obtain stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of our common stock on July 26, 2019. The minimum price at which we can sell shares under the Aspire Purchase Agreement is $0.50. On July 29, 2019, we issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. We recorded the fair value of the shares at July 29, 2019 of $603,924 as an expense in the third quarter of 2019. Concurrently with the Aspire Purchase Agreement, we entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement. In accordance with the Registration Rights Agreement, on August 20, 2019 we filed a Registration Statement on Form S-1 (File No. 333-232988) to cover the resale of the Commitment Shares and any Purchased Shares issuable to Aspire Capital under the Aspire Purchase Agreement. There is market uncertainty regarding the utilization of financing associated from the Aspire Purchase Agreement. As of September 30, 2019, no Purchase Shares were sold to Aspire Capital under the Aspire Purchase Agreement.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (12,554)	$ (1,252)
Net cash provided by investing activities	29,107	–
Net cash provided by financing activities	750	1,219
Net increase (decrease) in cash and cash equivalents	$ 17,303	$ (33)

Net Cash Used in Operating Activities

Net cash used in operating activities was $12.6 million and $1.3 million for the nine months ended September 30, 2019 and 2018, respectively. The increase in cash used in operating activities of $11.3 million was primarily due to the increase in research and development costs, increase in general and administrative expenses including payment of Merger related costs, and payments of liabilities that had built up prior to the Merger as compared to the prior year.

Net Cash Provided by Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019 was due to the receipt of net proceeds from the issuance of common stock of $0.8 million.

Net cash provided by financing activities for the nine months ended September 30, 2018 was primarily due to the receipt of net proceeds of $1.2 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 September 30, 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 September 30, 2019	Total	Less than one year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Milestone payments	550	110	220	220	–
Total contractual obligations	$ 550	$ 110	$ 220	$ 220	$ –

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

Purchase Commitments

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

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 nine months ended September 30, 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 September 30, 2019, we had cash equivalents of $17.4 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, whereas PDS Biotechnology Corporation, which prior to the Merger was a private, non-reporting operating company was not. Our company has an appropriate structure for internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We, and our subsidiaries, are not currently a party to, and our property is not currently the subject of, any material pending legal proceedings; however, we may become involved in various claims and legal actions arising in the ordinary course of business.

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. The risk factors set forth below contain material changes from, or additions to, the risk factors previously disclosed and included in our Quarterly Report on Form 10-Q for the three months ended March 31, 2019, as supplemented by the risk factors previously disclosed and included in our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2019.

Risks Related to Our Business, Financial Position and Capital Requirements

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 September 30, 2019, we had an accumulated deficit of $23.8 million. In July 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, at our discretion, Aspire Capital is committed to purchase up to an aggregate of $20.0 million of shares of our common stock, or the Purchased Shares, over the 30-month term of the Aspire Purchase Agreement. The minimum price at which we can sell shares under the Aspire Purchase Agreement is $0.50. On July 29, 2019, we issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. Concurrently with the Aspire Purchase Agreement, we entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement. In accordance with the Registration Rights Agreement, on August 20, 2019 we filed a Registration Statement on Form S-1 (File No. 333-232988) to cover the resale of the Commitment Shares and any Purchased Shares issuable to Aspire Capital under the Aspire Purchase Agreement. As of September 30, 2019, no Purchase Shares were sold to Aspire Capital under the Aspire Purchase Agreement. Further, our use of the Aspire Purchase Agreement is subject to certain additional limitations set forth elsewhere in this report. As such, our ability to use the Aspire Purchase Agreement to raise capital is uncertain.

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

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

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

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

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

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

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

Our future financial performance and our ability to commercialize PDS0101 and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of September 30, 2019, we had 14 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.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

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

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

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

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

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

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

- HIPAA, as amended by the HITECH Act, and its respective implementing regulations, including the final omnibus rule published on January 25, 2013, which imposes requirements relating to the privacy, security and transmission of individually identifiable health information for "covered entities" and "business associates." Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.

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

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

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

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

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

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

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

General Market Risk Factors

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 September 30, 2019, we had 5,278,850 shares of common stock outstanding. Approximately 3,460,000 of such shares are freely tradable, without restriction, in the public market. Approximately 1,817,000 of such shares of common stock are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

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

Our executive officers and directors and their affiliates beneficially own or control approximately 31% of the outstanding shares of our common stock as of September 30, 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.

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

There were no unregistered sales of the Company's equity securities during the three months ended September 30, 2019.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

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

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
10.1**	Amendment No. 1 to Clinical Trial Collaboration and Supply Agreement, dated as of October 28, 2019, by and between PDS Biotechnology Corporation and MSD International GmbH.
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.

** Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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

November 7, 2019 By: /s/ Frank Bedu-Addo
Frank Bedu-Addo
President and Chief Executive Officer
(Principal Executive Officer)

November 7, 2019 By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

AMENDMENT NO. 1 TO CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This Amendment No. 1 ("**Amendment No. 1**") to the Agreement (as defined below), made as of October 28, 2019 ("**Amendment Effective Date**"), is by and between MSD International GmbH, having a place of business at Weystrasse 20, 6006 Luzern, Switzerland ("**Merck**") and PDS Biotechnology Corporation, having a place of business at 303A College Road East, Princeton, NJ 08540 USA ("**PDS**"). Merck and PDS are each referred to herein individually as "**Party**" and collectively "**Parties**".

RECITALS

A. WHEREAS, the Parties entered into that certain Clinical Trial Collaboration and Supply Agreement dated as of May 19, 2017 (the "**Agreement**");

B. WHEREAS, the Parties desire to amend the Agreement to modify the following: (a) Protocol for the Study; (b) supply and delivery schedule of the PDS Compound and the Merck Compound, and (c) Data Sharing and Sample Testing Schedule to complete the Study as per the amended Protocol; all on the terms and conditions set forth in this Amendment No. 1;

NOW, THEREFORE, the Parties hereby agree as follows:

1. Certain Definitions. Capitalized terms used in this Amendment No. 1 and not defined herein shall have the meanings given to them in the Agreement.

2. Amendment to the Agreement. The Agreement is hereby amended as follows:

2.1 Section 1.76 of the Agreement shall be deleted in its entirety and replaced with the following:

""**Study**" means the Phase II clinical trial described in the Protocol to evaluate the safety, and preliminary efficacy of the concomitant and/or sequenced administration of the combination of the Merck Compound and the PDS Compound as a first line treatment in subjects with recurrent and/or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection."

2.2 Section 3.7.1 of the Agreement shall be deleted in its entirety and replaced with the following:

"The Joint Development Committee will agree as to which Party shall perform Sample Testing. Each Party shall use the Samples only for the Sample Testing and each Party shall conduct the Sample Testing solely in accordance with the Data Sharing and Sample Testing Schedule and the Protocol. Merck shall [***]. Merck shall provide to PDS the Sample Testing Results for the Sample Testing conducted by or on behalf of Merck, in electronic form or other mutually agreeable alternate form, to the extent specified on the Data Sharing and Sample Testing Schedule and on the timelines specified in the Data Sharing and Sample Testing Schedule or as otherwise mutually agreed."

2.3 The first paragraph of Section 4.1 of the Agreement shall be deleted in its entirety and replaced with the following:

"4.1 *Protocol.* A Protocol has been agreed upon by the Parties as of the Amendment Effective Date and is attached hereto as Appendix A. Through the JDC, PDS shall: (a) provide a draft of any subsequent revisions to the Protocol to Merck for Merck's review and comment; (b) submit a draft statistical analysis plan to Merck for Merck's review, comment and approval; (c) consider in good faith any further changes to the draft of the Protocol or statistical analysis plan requested by Merck; (d) incorporate any changes requested by Merck with respect to Merck Compound; and, (e) once a final version of the Protocol or statistical analysis plan, incorporating all comments is ready, submit the revised Protocol or statistical analysis plan to the JDC for final approval. To the extent the JDC cannot agree unanimously regarding the contents of the Protocol or statistical analysis plan for final approval: (i) PDS shall have final decision-making authority with respect to matters in the Protocol or statistical analysis plan related to the PDS Compound; (ii) Merck shall have final decision-making authority with respect to matters in the Protocol or statistical analysis plan related to the Merck Compound (including with respect to the quantities and/or presentations of Merck Compound to be provided for the Study and/or the timing for Delivery thereof); and (iii) all other matters in respect of the Protocol or statistical analysis plan on which the JDC cannot agree shall be resolved in accordance with Section 3.10.3. Once the final Protocol or statistical analysis plan have been approved in accordance with this Section 4.1, any material changes to such approved final Protocol or statistical analysis plan (other than material changes relating solely to the PDS Compound) and any changes to the final Protocol or statistical analysis plan (whether or not material) relating to the Merck Compound shall require Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [***] Business Days after Merck receives a copy of PDS' requested changes."

2.4 The contact information for PDS set forth in Article 22 of the Agreement shall be deleted in its entirety and replaced by the following:

"If to PDS, to: PDS Biotechnology Corporation
303A College Road East
Princeton, NJ 08540 USA
Attention: Frank Bedu-Addo
Phone: +1 (800) 208-3343
Facsimile: +1 (908) 790-1212"

2.5 Appendix A to the Agreement shall be deleted in its entirety and replaced with the new Appendix A attached to this Amendment No. 1.

2.6 Appendix B to the Agreement shall be deleted in its entirety and replaced with the new Appendix B attached to this Amendment No. 1.

2.7 Schedule I to the Agreement shall be deleted in its entirety and replaced with the new Schedule I attached to this Amendment No. 1

3. General. Except as specifically modified or amended by this Amendment No. 1, the terms and conditions of the Agreement remain unchanged and in full force and effect. All references in the Agreement to the "Agreement" shall mean the Agreement as modified by this Amendment No. 1. This Amendment No. 1 shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles. This Amendment No. 1 may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to the Agreement to be signed by their respective duly-authorized representatives as of the Amendment Effective Date.

PDS BIOTECHNOLOGY CORPORATION

By: /s/ Frank Bedu-Addo
Name: Frank Bedu-Addo
Title: President & CEO

MSD International GmbH

By: /s/ Franz Escherich
Name: Franz Escherich
Title: Director

Appendix A

PROTOCOL

[***]

Appendix B

Supply of Compounds

[***]

Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[***]

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 September 30, 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: November 7, 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 September 30, 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: November 7, 2019

/s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial and Accounting 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 September 30, 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: November 7, 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 September 30, 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: November 7, 2019

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