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 June 30, 2020

☐ **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.)

25B Vreeland Road, Florham Park, NJ 07932
(Address of principal executive offices)

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00033 per share	PDSB	Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the 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 ☒

The number of shares of the registrant's Common Stock, par value $0.00033 per share, outstanding as of August 6, 2020 was 15,361,619.

PDS BIOTECHNOLOGY CORPORATION

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2020

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,934,495	$ 12,161,739
Prepaid expenses and other	2,506,646	2,308,462
Total current assets	19,441,141	14,470,201
Property and equipment, net	13,247	21,051
Right-to-use asset	638,831	–
Total assets	$ 20,093,219	$ 14,491,252
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,092,527	$ 1,197,720
Accrued expenses	1,194,358	1,097,640
Restructuring reserve	126,862	498,185
Operating lease liability - short term	112,657	–
Total current liabilities	2,526,404	2,793,545
Noncurrent liability:		
Operating lease liability - long term	552,326	–
STOCKHOLDERS' EQUITY		
Common stock, $0.00033 par value, 75,000,000 shares authorized at June 30, 2020 and December 31, 2019, 15,361,619 shares and 5,281,237 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	5,064	1,742
Additional paid-in capital	52,861,882	40,633,670
Accumulated deficit	(35,852,457)	(28,937,705)
Total stockholders' equity	17,014,489	11,697,707
Total liabilities and stockholders' equity	$ 20,093,219	$ 14,491,252

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development expenses	$ 1,414,225	$ 1,886,934	$ 3,385,904	$ 2,916,937
General and administrative expenses	1,521,736	2,383,972	3,581,884	6,289,848
Total operating expenses	2,935,961	4,270,906	6,967,788	9,206,785
Loss from operations	(2,935,961)	(4,270,906)	(6,967,788)	(9,206,785)
Other income (expense):				
Gain on bargain purchase upon merger	–	209,449	–	11,939,331
Interest income	6,617	175,605	53,036	198,907
Interest expense	–	–	–	(606)
Net (loss) income and comprehensive (loss) income	(2,929,344)	(3,885,852)	(6,914,752)	2,930,847
Per share information:				
Net (loss) income per share, basic	$ (0.19)	$ (0.75)	$ (0.54)	$ 0.66
Net (loss) income per share, diluted	$ (0.19)	$ (0.75)	$ (0.54)	$ 0.52
Weighted average common shares outstanding, basic	$ 15,357,199	$ 5,175,837	$ 12,835,980	$ 4,466,025
Weighted average common shares outstanding, diluted	$ 15,357,199	$ 5,175,837	$ 12,835,980	$ 5,677,360

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

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

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares Issued	Amount			
Balance - March 31, 2019	5,172,938	$ 1,707	$ 38,642,411	$ (14,196,475)	$ 24,447,643
Stock based compensation expense	–	–	18,580	–	18,580
Issuance of common stock, net of issuance costs	4,549	2	25,242	–	25,244
Net loss	–	–	–	(3,885,852)	(3,885,852)
Balance - June 30, 2019	5,177,487	$ 1,709	$ 38,686,233	$ (18,082,327)	$ 20,605,615

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares Issued	Amount			
Balance - March 31, 2020	15,350,445	$ 5,064	$ 52,805,601	$ (32,923,113)	$ 19,887,552
Stock-based compensation expense	–	–	46,113	–	46,113
Issuance of common stock from 401K match	11,174	–	10,168	–	10,168
Net loss	–	–	–	(2,929,344)	(2,929,344)
Balance - June 30, 2020	15,361,619	$ 5,064	$ 52,861,882	$ (35,852,457)	$ 17,014,489

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

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

(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Equity
	Shares Issued	Amount	Capital	Deficit	(Deficit)
Balance - December 31, 2018	3,417,187	$ 1,128	$ 19,311,529	$ (21,013,174)	$ (1,700,517)
Stock based compensation expense	–	–	2,773,451	–	2,773,451
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	4,549	2	25,241	–	25,243
Equity from merger transaction	1,599,178	528	15,793,110	–	15,793,638
Net income	–	–	–	2,930,847	2,930,847
Balance - June 30, 2019	5,177,487	$ 1,709	$ 38,686,233	$ (18,082,327)	$ 20,605,615

	Common Stock		Additional Paid-in	Accumulated	Total Equity
	Shares Issued	Amount	Capital	Deficit	(Deficit)
Balance - December 31, 2019	5,281,237	$ 1,742	$ 40,633,670	$ (28,937,705)	$ 11,697,707
Stock-based compensation expense	–	–	171,106	–	171,106
Issuance of common stock, net of issuance costs	10,000,000	3,299	11,966,703	–	11,970,002
Issuance of common stock for convertible debt	65,240	22	70,437	–	70,459
Issuance of common stock from 401K match	15,142	1	19,966	–	19,967
Net loss	–	–	–	(6,914,752)	(6,914,752)
Balance - June 30, 2020	15,361,619	$ 5,064	$ 52,861,882	$ (35,852,457)	$ 17,014,489

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net (loss) income	$ (6,914,752)	$ 2,930,847
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Stock-based compensation expense	171,106	2,773,451
Stock-based 401K company common match	19,967	25,244
Depreciation expense	7,805	62,706
Amortization of the right-to-use asset	41,800	–
Bargain purchase gain from merger	–	(11,939,331)
Changes in assets and liabilities:		
Prepaid expenses and other assets	(198,184)	157,273
Accounts payable	(105,193)	(1,157,171)
Accrued expenses	96,718	(292,678)
Restructuring reserve	(371,323)	(786,396)
Cash payments for expenses:		
Payments made for operating lease	(15,649)	–
Net cash used in operating activities	(7,267,705)	(8,226,055)
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:		
Proceeds from exercise of warrants	70,459	–
Proceeds from issuance of common stock, net of issuance costs	11,970,002	750,000
Net cash provided by financing activities	12,040,461	750,000
Net increase in cash and cash equivalents	4,772,756	21,630,457
Cash and cash equivalents at beginning of period	12,161,739	103,695
Cash and cash equivalents at end of period	$ 16,934,495	$ 21,734,152
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ –	$ 606
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 AND SUBSIDIARIES
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"), PDS is a clinical-stage immunotherapy company developing a growing pipeline of cancer immunotherapies and infectious disease vaccines designed to overcome the well-established limitations of current immunotherapy technologies. PDS owns Versamune®, a proprietary T-cell activating platform designed to train the immune system to better attack and destroy disease. When paired with an antigen, a disease-related protein that is recognizable by the immune system, Versamune® has been shown to induce, *in vivo,* large quantities of high-quality, highly potent polyfunctional CD8+ killer T-cells, a specific sub-type of CD8+ killer T-cell that is more effective at killing infected or target cells. Our immuno-oncology products can potentially be used as a component of combination products with other leading technologies to provide effective treatments across a range of cancer types, including Human Papillomavirus (HPV)-based cancers, melanoma, colorectal, lung, breast and prostate cancers or as monotherapies in early-stage disease. PDS is working to expand its infectious disease pandemic development program, including novel vaccines for COVID-19 and universal influenza, in addition to its previously announced tuberculosis development collaboration with Farmacore Biotechnology.

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

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 (the "Merger Agreement"), 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 was 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.

In December 2019, a coronavirus known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease, known as COVID-19, that has now spread globally. On January 30, 2020 the World Health Organization (WHO) declared COVID-19 a pandemic (the "COVID-19 Pandemic"). The Secretary of Health and Human Services declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the COVID-19 Pandemic. The full impact of the COVID-19 Pandemic is unknown and rapidly evolving. To date, two of the three currently planned PDS0101 clinical trials have been delayed, specifically as a result of the adverse impact the COVID-19 Pandemic has had on clinical trial operations for cancer indications in the United States.

Note 2 – Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at June 30, 2020, the statements of operations and comprehensive loss and changes in stockholders' equity for the three and six months ended June 30, 2020 and 2019, and cash flows for the six months ended June 30, 2020 and 2019 are unaudited. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, in accordance with 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 six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The balance sheet as of December 31, 2019 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 Company's audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2019, filed by the Company with the SEC in its Annual Report on Form 10-K on March 27, 2020.

(B) Use of estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses at the date of the consolidated financial statements and during the reporting periods, and to disclose contingent assets and liabilities at the date of the consolidated financial statements. Actual results could differ from those estimates.

(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 ability to preserve its cash resources, the Company's review of strategic alternatives, 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, the Company's ability to raise capital, and the effects of health epidemics, pandemics, or outbreaks of infectious diseases, including the recent COVID-19 pandemic.

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) Business acquisition:

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

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

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

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

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

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

(E) 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.

(F) Research and development:

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

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

(G) Patent costs:

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

(H) Intangible asset and impairment:

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

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

(I) Stock-based compensation:

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, directors and non-employees to be recognized as expense in the condensed statements of operations and comprehensive loss based on their grant date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. This model requires the following assumptions: (1) the expected volatility of our stock is based on volatilities of a peer group of similar companies in the biotechnology industry whose share prices are publicly available, (2) the expected term of the award is based on the simplified method, which is the midpoint between the requisite service period and the contractual term of the option, as we have a limited history of being a public company from March 15, 2019 (the date of the Merger) to develop reasonable expectations about future exercise patterns and employment duration for our options, (3) the risk-free interest rate based on U.S. Treasury notes with a term approximating the expected life of the option and (4) expected dividend yield of 0, since we have never paid cash dividends and have no present intention to pay cash dividends.

The Company expenses the fair value of its stock-based compensation awards to employees, directors and non-employees on a straight-line basis over the requisite service period, which is generally the vesting period. The Company recognizes forfeitures as they occur.

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

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

The common stock issuable upon the conversion or exercise of the following dilutive securities as of June 30, 2020 has been excluded from the diluted net loss per share attributable to common stockholders calculation because their effect would have been antidilutive for the period presented.

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

	As of June 30,	
	2020	2019
Stock options to purchase Common Stock	1,639,753	1,418,301
Warrants to purchase Common Stock	197,518	262,758
Total	1,837,271	1,681,059

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator				
Basic and diluted net (loss) income	$ (2,929,344)	$ (3,885,852)	$ (6,914,752)	$ 2,930,847
Denominator				
Shares used in computing basic net (loss) income per share	15,357,199	5,175,837	12,835,980	4,466,025
Shares from dilutive securities	–	–	–	1,211,335
Shares used in computing diluted net (loss) income per share	15,357,199	5,175,837	12,835,980	5,677,360
Net (loss) income per share, basic	$ (0.19)	$ (0.75)	$ (0.54)	$ 0.66
Net (loss) income per share, diluted	$ (0.19)	$ (0.75)	$ (0.54)	$ 0.52

(K) 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 for office space located in Berkeley Heights, New Jersey. The lease for property in Berkeley Heights was subsequently terminated. As of March 5, 2020 the Company entered into a new sub lease for office space at Florham Park commencing May 1, 2020. See note 6 for details.

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. As of June 30, 2020, there is an active lease accounted for under ASC 842.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) ("ASU 2018-13"). ASU 2018-13 modifies disclosure requirements related to fair value measurement. On January 1, 2020, the Company adopted ASU 2018-07 and there was no impact to its financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40) ("ASU 2018-15"). ASU 2018-15 reduces complexity for the accounting for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). On January 1, 2020, the Company adopted ASU 2018-07 and there was no impact to its financial statements

Note 3 – Liquidity

As of June 30, 2020, the Company had $16.9 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 and net proceeds of $12.8 million from the sale of our common stock. 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.

In July 2019, the Company 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 the Company's discretion, Aspire Capital is committed to purchase up to an aggregate of $20.0 million of shares of the Company's common stock (the "Purchased Shares"), over the 30-month term of the Aspire Purchase Agreement. 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. On July 29, 2019, the Company issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement. As of June 30, 2020 no shares have been sold to Aspire.

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

On July 22, 2020, the Company filed a shelf registration statement (the "2020 Shelf Registration Statement"), with the SEC, for the issuance of common stock, preferred stock, warrants, rights, debt securities and units (collectively, the "Shelf Securities"), up to an aggregate amount of $100 million. The 2020 Shelf Registration Statement was declared effective on July 31, 2020. On August 13, 2020, the Company sold 6,900,000 shares of its common stock at a public offering price of $2.75 per share pursuant to the 2020 Shelf Registration Statement, which includes 900,000 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. The Company received gross proceeds of approximately $19.0 million and net proceeds of approximately $17.1 million, after deducting underwriting discounts and offering expenses. Approximately $81,000,000 of Shelf Securities remain available for future sale under the 2020 Shelf Registration Statement.

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.

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. The Company's budgeted cash requirements in 2020 and beyond include expenses related to continuing development and clinical studies. Based on the Company's available cash resources and cash flow projections as of the date the consolidated financial statements were available for issuance, the Company believes there are sufficient funds to continue operations and research and development programs for at least 12 months from the date of this report. Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. These financial resources may not be adequate to sustain its operations.

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

Note 4 – Reverse Merger

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

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

For accounting purposes, Private PDS is considered to be the accounting acquirer in the Merger because Private PDS's stockholders owned approximately 70% of PDS'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 Merger Agreement, 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 the closing of the Merger, 753 of in-the-money options and 235 fractional shares paid out in cash to shareholders were not issued as common stock, resulting in 1,599,178 common shares issued.

Final Purchase Price Allocation

The Company completed its analysis of the allocation of the purchase price in the fourth quarter of 2019. The purchase price was allocated to the net assets acquired of Edge based upon their preliminary estimated fair values as of March 15, 2019. The in-process research and development asset ("IPR&D") that is recognized relates to Edge's NEWTON 2 clinical trial for EG-1962 that has not reached technological feasibility. The Company was actively looking to license out EG-1962 and had preliminary discussions with third parties who were actively looking at the data of EG-1962 during the prior year. Accordingly, the IPR&D was initially 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 initially recognized an indefinite life deferred tax liability. During the three months ended June 30, 2019, two adjustments were made to the preliminary allocation. The first was for $275,000 relating to an offer to purchase equipment that was given a value of $0 in the preliminary allocation. The second was for $65,551 relating to Edge's bonus plan that was effective prior to the date of acquisition. During the three months ended December 31, 2019 two additional adjustments were made to the preliminary valuation. The first was for an increase of $1,751,000 relating to the IPR&D in which the Company finalized the valuation of the IPR&D and as a result recognized an additional deferred tax liability of $224,513. The second was for a write-off relating to a transition service arrangement that was effective prior to the date of the acquisition for $131,250. In accordance with ASC 805, Business Combinations any the excess of the fair value of the acquired net assets over the purchase price has been recognized as a bargain purchase gain in the consolidated statement of operations and comprehensive loss. The Company has reassessed whether all the assets acquired, and the liabilities assumed have been identified and recognized in the purchase price allocation.

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

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

(1) Due to the aforementioned purchase price adjustments subsequent to March 31, 2019, the preliminary estimate of the bargain purchase gain was adjusted from $11,729,882 and finalized for the year ended December 31, 2019 at $13,334,568.

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.

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

Note 5 – Fair Value of Financial Instruments

There were no transfers among Levels 1, 2, or 3 during 2020 or 2019.

	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 June 30, 2020: (unaudited)				
Cash and cash equivalents	$ 16,934,495	$ 16,934,495	$ –	$ –
As of December 31, 2019:				
Cash and cash equivalents	$ 12,161,739	$ 12,161,739	$ –	$ –

Note 6 – Leases

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 was 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 in the third quarter of 2019. 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. 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 entered into a new lease for permanent office space. This lease was terminated on May 31, 2020.

Effective March 5, 2020, the Company entered into a sublease for approximately 11,200 square feet of office space located at 25B Vreeland Road, Florham Park, NJ. The sublease commenced on May 1, 2020 and will continue for a term of forty (40) months with an option to renew through October 31, 2027. Upon inception of the lease, the Company recognized approximately $0.7 million of a ROU asset and operating lease liabilities. The discount rate used to measure the operating lease liability as of May 1, 2020 was 9.15%. Throughout the period described above the Company has maintained, and continues to maintain, a month-to-month lease for its research facilities at the Princeton Innovation Center BioLabs located at 303A College Road E, Princeton NJ, 08540.

	Six Months Ended June 30, 2020
Cash paid for amounts included in measurement of lease liabilities:	
Operating cash outflows for operating lease	$ 15,649
Right-of use asset obtained in exchange for new operating lease liability	$ 638,831
Remaining lease term - operating lease liability	38.0
Discount rate - operating lease	9.15%
Reported as of June 30, 2020	
Current portion of operating lease liability	$ 112,657
Operating leases, net of current portion	552,326
Total	$ 664,983

Note 7 – Accrued Expenses and Restructuring Reserve

Accrued expenses and other liabilities consist of the following:

	As of June 30, 2020	As of December 31, 2019
Accrued research and development costs	$ 147,841	$ 16,415
Accrued professional fees	135,641	256,062
Accrued compensation	910,876	603,229
Accrued rent	–	221,934
Total	$ 1,194,358	$ 1,097,640

Restructuring Reserve

	As of June 30, 2020	As of December 31, 2019
Restructuring reserve (1)	$ 126,862	$ 498,185
Total	$ 126,862	$ 498,185

(1) Restructuring reserve relates to the severance costs incurred by Edge prior to the Merger and assumed by the Company as part of the purchase accounting, but not yet paid. The severance costs continue through September 2020. For the six months ended June 30, 2020, the Company paid $371,323 of restructuring expense which was previously recorded on Edge's financials.

Note 8 – Stock-Based Compensation

The Company has four equity compensation plans: the 2009 Amended Stock Option Plan, the 2010 Equity Incentive Plan, the 2014 Equity Incentive Plan and the 2018 Stock Incentive Plan (the "Plans"). Originally, the Company was able to grant up to 27,410 of Common Stock as both incentive stock options ("ISOs") and nonqualified stock options ("NQs") under the 2010 Equity Incentive Plan. 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. As of June 30, 2020 there were 190,799 shares available for grant under the 2018 Stock Incentive Plan.

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

The Board has reserved 200,000 shares of the Company's common stock for issuance pursuant to non-qualified stock options granted under the 2019 Inducement Plan, and the 2019 Inducement Plan will be administered by the Compensation Committee of the Board. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, non-qualified stock options under the 2019 Inducement Plan may only be made to an employee who has not previously been an employee or member of the Board (or any parent or subsidiary of the Company), or following a bona fide period of non-employment by the Company (or a parent or subsidiary of the Company), if he or she is granted such non-qualified stock options in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. As of June 30, 2020, there were 121,500 shares available for grant under the 2019 Inducement Plan.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Stock-Based Compensation				
Research and development	$ 53,842	$ 9,387	$ 106,526	$ 450,087
General and administrative	(7,728)	9,193	64,580	2,323,364
Total	$ 46,113	$ 18,580	$ 171,106	$ 2,773,451

The fair value of options granted during the three and six months ended June 30, 2020 and the three and six months ended June 30, 2019 was estimated using the Black-Scholes option valuation model utilizing the following assumptions.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
	(unaudited)		(unaudited)	
Volatility	97.13%	94.43%	97.00%	88.87%
Risk-Free Interest Rate	0.34%	2.19%	0.38%	2.34%
Expected Term in Years	6.07	6.08	6.07	6.17
Dividend Rate	0.00%	0.00%	0.00%	0.00%
Fair Value of Option on Grant Date	$ 1.11	$ 4.77	$ 1.10	$ 5.31

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, 2019	1,421,797	$ 15.95		
Granted	319,907	1.43		
Exercised	–	–		
Forfeited	(84,227)	41.34		
Expired	(17,724)	4.69		
Options outstanding at June 30, 2020	1,639,753	$ 11.94	7.17	$ 184,693–
Vested and expected to vest at June 30, 2020	1,639,753	$ 11.94	7.17	$ 184,693–
Exercisable at June 30, 2020	1,047,284	$ 16.73	5.84	$ –

At June 30, 2020 there was approximately $1,554,689 of unamortized stock option compensation expense, which is expected to be recognized over a remaining average vesting period of 3.39 years.

Note 9 – 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 2020 and there will be no current income tax expense. Additionally, there was a full valuation allowance against the net deferred tax assets as of June 30, 2020 and December 31, 2019. 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 six months ended June 30, 2020 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 June 30, 2020, 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 six months ended June 30, 2020 and for the year ended December 31, 2019.

Note 10 – Commitments and Contingencies

Employment Matters

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

Rent

For month-to-month arrangements not impacted by the adoption of ASC 842, rent for the three and six months ended June 30, 2020 was $46,337 and $104,978 compared to the three and six months ended June 30, 2019 of $11,400 and $ 20,300.

Note 11 – Retirement Plan

The Company has a 401(k) defined contribution plan as a benefit for all employees and permits voluntary contributions by employees subject to IRS-imposed limitations. Employer 401K contributions for the three and six months ended June 30, 2020 was $10,168 and $19,966, respectively, compared to the three and six months ended June 30, 2019 of $25,242.

Note 12– Subsequent Events

On August 13, 2020, the Company sold 6,900,000 shares of its common stock at a public offering price of $2.75 per share pursuant to the 2020 Shelf Registration Statement, which includes 900,000 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. The Company received gross proceeds of approximately $19.0 million and net proceeds of approximately $17.1 million, after deducting underwriting discounts and offering expenses.

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 the Company as of and for the year ended December 31, 2019 on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 27, 2020. As further described in "Note 1 – Nature of Operations" and "Note 4 – 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 the need 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;
- unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19;
- 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 immunotherapy company developing a growing pipeline of cancer immunotherapies and infectious disease vaccines designed to overcome the well-established limitations of current immunotherapy technologies. PDS owns Versamune®, a proprietary T-cell activating platform designed to train the immune system to better attack and destroy disease. When paired with an antigen, a disease-related protein that is recognizable by the immune system, Versamune® has been shown to induce, *in vivo,* large quantities of high-quality, highly potent polyfunctional CD8+ killer T-cells, a specific sub-type of CD8+ killer T-cell that is more effective at killing infected or target cells.

The induction of CD8+ (killer) T-cells is important to achieving robust long-term efficacy in most infectious disease vaccines and efficacy in cancer immunotherapy. Current preventive and prophylactic vaccine approaches and technologies predominantly focus on creating strong induction of antibody responses. However, the induction of T-cell responses, in addition to antibody responses, provides more durable and broad protection against infectious diseases. Similarly, it is well documented that the most critical attribute of an effective cancer immunotherapy is 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 impeding the achievement of durable efficacy of immunotherapy.

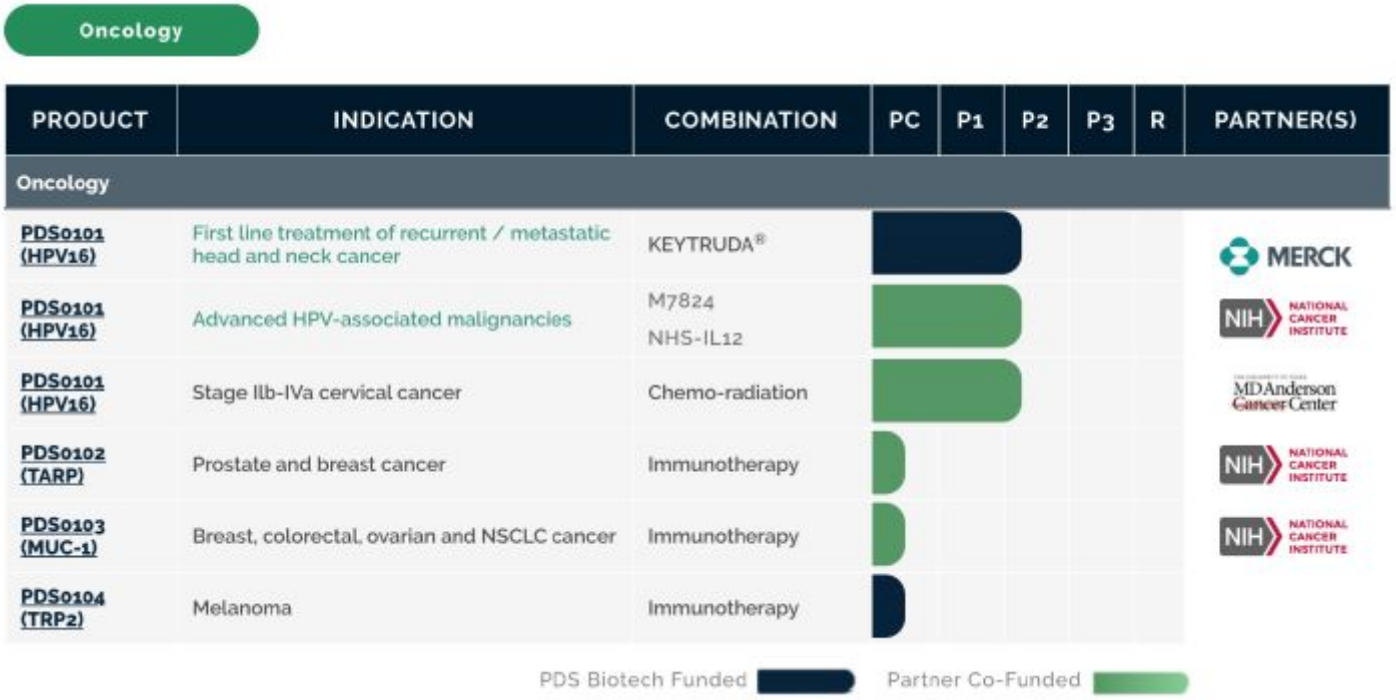
PDS's lead clinical stage program, PDS0101, has demonstrated unique *in-vivo* induction of high levels of active HPV-specific CD8+ T-cells in humans, confirming impressive preclinical CD8+ T-cell study results, as well as successful induction of CD8+ T-cells against a viral target (HPV). This strong CD8+ T-cell induction data, coupled with preclinical data demonstrating the induction of high levels of neutralizing antibody responses, suggested strong potential to successfully develop and progress novel Versamune®-based vaccines to treat infectious diseases, and thus informed PDS' subsequent pipeline expansion into multiple infectious disease indications.

Versamune® activates an important immunological signaling pathway, critical to induction of robust and sustained anti-viral and anti-tumor immune responses, known as the Type I interferon (IFN) signaling pathway. Versamune® has demonstrated the following:

- Prolonged and localized induction of chemokines and cytokines within lymph nodes, resulting in sustained recruitment of B cells and T cells, enhanced potency, and minimized risk of systemic toxicity, resulting in an improved safety profile in clinical and preclinical safety/toxicology studies.
- Dramatic enhancement of antibody titers in the context of dose sparing of multiple antigens.
- Induction of polyfunctional, highly potent antigen-specific CD8+ T-cells associated with the type of long-term memory responses necessary to for effective cancer immunotherapy and also to provide long term protection against viral infection.
- Demonstrated high levels of antigen-specific antibody, and CD8+ and CD4+ T cell responses within 2 weeks of a single vaccination in human clinical studies.
- Spontaneously forming spherical nanoparticles composed of a single synthetic lipid; a process that results in relatively low projected commercial cost of goods and potential for rapid commercial scale-up.

Finally, Versamune®'s immunostimulatory properties have been confirmed in preclinical studies and may be administered with a diverse array of antigens, including recombinant proteins, peptides, DNA and RNA antigens. The mechanism of action was published in the Journal of Immunology in June 2019.

We believe that the Versamune® platform has shown strong potential to become an industry-leading immunotherapy technology; it is the platform technology underpinning PDS' robust pipeline of cancer immunotherapies and infectious disease vaccines. We expect substantial value accretion as our pipeline products successfully progress through Phase 2 clinical trials; two of the three currently planned PDS0101 clinical trials have been delayed, specifically as a result of the adverse impact the COVID-19 pandemic has had on clinical trial operations for cancer indications in the United States.



The unique combination of high potency and excellent safety of the Versamune® platform observed in preclinical studies appears to have been corroborated in the successfully-completed 12-patient PDS0101 Phase 1/2a clinical trial. On September 19, 2019, PDS reported retrospective clinical outcome data from this study. Despite most of the patients being infected with multiple HPV strains other than HPV 16, regression was seen in 8 out of 10 patients, with complete regression of pre-cancerous lesions documented in 6 out of 10 patients at their first post-treatment evaluation, which occurred within 1-3 months of completing treatment. In addition, the fact that no disease recurrence occurred over the two-year evaluation period strongly suggested a robust and durable therapeutic immune response due to the induction of T-cells by PDS0101 administration that were clinically active. As a result of this information strongly suggesting the unique ability of PDS0101 to generate potent and biologically active CD8+ T-cells *in-vivo*, PDS focused its clinical strategy on areas of more severe unmet medical need in which PDS0101 is combined with other immune-modulating agents, including checkpoint inhibitors and standard of care e.g. chemoradiotherapy, to provide improved clinical benefit to patients.

We believe that rational design of combination immunotherapies using agents that promote synergy with each other and reduce the 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 to promote strong CD8+ T-cell induction, while also altering the tumor microenvironment to make tumors more susceptible to T-cell attack, which PDS believes makes it an ideal complement to checkpoint inhibitors and other immune-modulating agents by enhancing their potency as part of combination therapies. 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 and other cancer treatments such as immune-cytokines and chemotherapy.

On October 28, 2019, we entered into an amendment to an existing clinical trial collaboration agreement with a subsidiary of Merck (known as MSD outside the United States and Canada) to evaluate a combination of our lead Versamune®-based immunotherapy, PDS0101, with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase 2 clinical trial. The planned clinical trial will evaluate the efficacy and safety of this therapeutic combination as a first-line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection. This amendment, primarily related to a modification to the original clinical trial design to evaluate PDS0101 in combination with KEYTRUDA® as first-line treatment, was the result of the FDA's approval, 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. This planned clinical trial previously anticipated to begin in June 2020, is currently on hold, primarily due to the effect of COVID-19 on clinical trial operations in the United States.

PDS previously announced a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) for development of the PDS0101 HPV cancer immunotherapy in combination with other immune-modulating agents as a potential treatment for advanced HPV-related cancers. Preclinical study results arising from this CRADA were recently published in the *Journal for ImmunoTherapy of Cancer*, *Immunomodulation to enhance the efficacy of and HPV therapeutic vaccine* (Journal for ImmunoTherapy of Cancer 2020;8:e000612. doi:10.1136/ jitc-2020-000612), indicating that PDS0101 generated both human papillomavirus (HPV)-specific T-cells and an associated antitumor response when used as a monotherapy. When PDS0101 was combined with two other novel development-stage anti-cancer agents, Bintrafusp alfa (M7824) and NHS-IL12, preclinical data suggested that all three therapeutic agents worked synergistically to provide enhanced tumor regression and T-cell response when compared to any of the agents alone.

In June 2020, the first patient was dosed under this PDS0101 CRADA, in a NCI-led Phase 2 clinical study evaluating PDS0101, NHS-IL12, and M7824, owned by EMD Serono (Merck KGaA). The study will evaluate the objective response rate of this novel triple combination in approximately 30 patients with advanced HPV-associated cancers.

In April 2020, the PDS0101 CRADA was expanded to include clinical and preclinical development of PDS0103. PDS0103 is an investigational immunotherapy owned by PDS and designed to treat cancers associated with the mucin-1 (MUC-1) oncogenic C-terminal region antigen such as ovarian, breast, colorectal and lung cancers. PDS0103 combines Versamune® with novel highly immunogenic agonist epitopes of MUC-1 developed by the NCI. PDS0103 is currently in late preclinical development.

We anticipate initiation, in the near term, of a third PDS0101 Phase 2 clinical study with The University of Texas MD Anderson Cancer Center. This clinical study will investigate the safety and anti-tumor efficacy of PDS0101 in combination with standard-of-care chemo-radiotherapy (CRT), and their correlation with critical immunological biomarkers in patients with locally advanced cervical cancer. PDS believes that Versamune®'s strong T-cell induction has potential to meaningfully enhance efficacy of the current standard of care CRT treatment in this indication.

PDS believes that the key differentiating attributes of the Versamune® platform technology, strong induction of CD8+ and CD4+ T-cells and antibodies, can also be leveraged to improve treatment and preventive options in several infectious disease indications. Specifically, the emerging COVID-19 pandemic has provided a unique opportunity to highlight Versamune®'s transformative immunostimulatory activities. Our newly-expanded infectious diseases pipeline now cover an expansive range of pathogens:

On December 4, 2019, we entered into an Amended and Restated Material Transfer Agreement (MTA) with the Brazilian pharmaceutical company Farmacore Biotechnology to develop a novel tuberculosis (TB) immunotherapy based on a combination of Farmacore's proprietary TB antigens with Versamune®. A preceding material transfer agreement, under which preliminary preclinical work was previously initiated, was thus amended and restated due to promising early preclinical results and to progress this program to the next development phase. In preliminary evaluations, our Versamune®-based TB product, PDS0201, demonstrated highly promising TB-specific T-cell induction *in-vivo*. Under the Farmacore MTA, PDS will undertake product development and Farmacore will conduct *in-vivo* preclinical studies evaluate product efficacy. The term of the agreement extends until the end of the initial product testing period. In June 2020, we announced a second collaboration with Farmcore to develop PDS0204, a vaccine to prevent COVID-19, combining Versamune® with Farmacore's recombinant SARS-CoV-2 antigen. Initial financial support for PDS0204 has been provided

by the Brazilian government. PDS and Farmacore plan to rapidly progress through preclinical development and into phase 1 clinical testing in Brazil in the near future.

PDS is advancing development of PDS0203, our leading COVID-19 vaccine candidate, which will combine Versamune® with SARS-CoV-2-specific proteins. Our goal is to advance a COVID-19 vaccine into human trials as quickly as possible; we are currently in active discussions with both government agencies and non-governmental organizations to determine the most accelerated path to advance PDS0203 into clinical trials.

PDS0203 is being designed to potentially provide long-term and broad protection against infection from COVID-19 and its potential mutations, based on Versamune®'s ability to prime the immune system to generate both antibodies for near term protection and T-cell responses for long term protection against pathogens. Preclinical data confirms that PDS0203 elicits induction of highly active and potent virus-specific CD8 killer and CD4 helper T-cells within 14 days of treatment. The study also demonstrated induction of the long-lasting virus-specific memory T-cells necessary for longer term protection. PDS0203 demonstrated a 30-45 fold increase in COVID-19 specific T-cells by Day 14 when compared to the vaccine without Versamune®. These preclinical studies also confirmed induction of strong anti-SARS-CoV-2 neutralizing antibodies within 14 days, with a 20-25-fold increase when compared to the vaccine without Versamune®. Lastly, these preclinical studies showed a further substantial increase in neutralizing antibody levels continuing more than 30 days after vaccination.

This broader projected range of effective immunity is a result of Versamune®'s unique ability to specifically activate Type I interferons (IFNs) critical to developing effective anti-viral immune responses, and also to promote presentation of the unique disease-associated protein or peptide to the appropriate compartment of the dendritic cells of the immune system. As a result of this capability, Versamune® has demonstrated enhanced immunogenicity in the context of dose sparing of both flu and COVID-19 antigens through strong induction of neutralizing antibodies. Finally, the simple chemical composition of PDS0203 is expected to permit rapid manufacturing scale-up for global deployment.

Based on the key characteristics of Versamune® described above, we are progressing development of PDS0202, a universal influenza vaccine, which combines Versamune® with novel influenza vaccine antigens. PDS0202 development is being supported by an agreement with the National Institute of Allergy and Infectious Diseases (NIAID) Collaborative Influenza Vaccine Innovation Centers (CIVICs) program, with a goal of rapidly progressing into a human clinical trial. Preclinical development studies will be performed at three sites: PDS' Princeton, NJ laboratories, The University of Kentucky School of Medicine, and the CIVICs Center for Influenza Vaccine Research for High-Risk Populations (CIVR-HRP). We anticipate that PDS0202 could provide broad and long-term protection against multiple influenza strains.

Since our inception in 2005, we have devoted substantially all 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 have never been profitable and have incurred net losses in each year since our inception. Our net losses were $7.0 million and $3.8 million for the years ended December 31, 2019 and 2018, respectively. As of June 30, 2020, we had an accumulated deficit of $32.9 million. Substantially all of our net losses have resulted from costs incurred in connection with its research and development programs and from general and administrative costs associated with these operations.

As of June 30, 2020, we had $16.9 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 our Versamune® platform;
- the outcome, timing and costs of seeking regulatory approvals;
- the impact of COVID-19 on company operations;
- 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-license or acquire 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-functional cancer immunotherapies and transformative infectious disease vaccines 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 4 – 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. The adverse impact of COVID-19 on research and development activities is being monitored closely including its impact on clinical trial initiation and enrollment.

We expect that our research and development expenses will increase significantly over the next several years as we advance our Versamune®-based immuno-oncology candidates into and through clinical trials, pursue 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 Versamune® based products. The probability of successful commercialization of our immuno-oncology and infectious disease candidates may be affected by numerous factors, including unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Results of Operations

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Increase (Decrease)	
	2020	2019	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 1,414	$ 1,887	$ (473)	(25)%
General and administrative expenses	1,522	2,384	(862)	(36)%
Total operating expenses	2,936	4,271	(1,335)	(31)%
Loss from operations	(2,936)	(4,271)	1,335	(31)%
Gain on bargain purchase	–	209	(209)	(100)%
Interest income, net	7	176	(169)	(96)%
Net loss and comprehensive loss	$ (2,929)	$ (3,886)	$ 957	(25)%

Research and Development Expenses

Research and development (R&D) expenses decreased to $1.4 million for the three months ended June 30, 2020 from $1.9 million for the three months ended June 30, 2019. The decrease of $0.5 is primarily attributable to a decrease of $0.5 in technical operations (manufacturing), $0.1 in regulatory expenses and $0.4 in clinical studies, offset by an increase of $0.4 in personnel costs and $0.1 in pre-clinical studies.

General and Administrative Expenses

General and administrative expenses decreased to $1.5 million for the three months ended June 30, 2020 from $2.4 million for the three months ended June 30, 2019. The decrease of $0.9 million is primarily attributable to a decrease of $0.2 million in personnel costs, $0.2 in legal fees, $0.1 in facilities and office expenses, $0.3 in insurance expense and $0.1 in professional fees.

Gain on Bargain purchase

Gain on Bargain Purchase was $0.0 for the three months ended June 30, 2020 and $0.2 million during the three months ended June 30, 2019. A decrease of $0.2 million as compared to the three months ended June 30, 2020, is due to the purchase price adjustments related to the Merger in March of 2019, resulting in 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

Interest income was $0.01 million for the three months ended June 30, 2020 and $0.18 million for the three months ended June 30, 2019. A decrease of $0.17 million due to interest received on invested cash and cash equivalents.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		Increase (Decrease)	
	2020	2019	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 3,386	$ 2,917	$ 469	16%
General and administrative expenses	3,582	6,290	(2,708)	(43)%
Total operating expenses	6,968	9,207	(2,239)	(24)%
Loss from operations	(6,968)	(9,207)	2,239	(24)%
Gain on bargain purchase	–	11,939	(11,939)	(100)%
Interest income, net	53	198	(145)	(73)%
Net (loss) income and comprehensive (loss) income	$ (6,915)	$ 2,931	$ (9,845)	(336)%

Research and Development Expenses

Research and development (R&D) expenses increased to $3.4 million for the six months ended June 30, 2020 from $2.9 million for the same period in 2019. The increase of $0.5 million was primarily attributable to an increase in personnel costs of $0.5 million, professional fees of $0.2 million and pre-clinical studies of $0.3 million, offset by decreases in technical operations (manufacturing) $0.2 million, regulatory consulting $0.1 million and clinical R&D of $0.2 million.

General and Administrative Expenses

General and administrative expenses decreased to $3.6 million for the six months ended June 30, 2020 from $6.3 million for the same period in 2019. The $2.7 million decrease was primarily attributable to decreases in personnel costs of $2.6 million, insurance costs of $0.2 million, legal fees of $0.3 million offset by an increase in professional fees of $0.4 million.

Gain on Bargain purchase

Gain on Bargain Purchase was $0.0 for the six months ended June 30, 2020 and $11.9 million during the six months ended June 30, 2019. A decrease of $11.9 million was due to the bargain purchase gain as a result of the Merger in March of 2019, resulting in 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

Interest income was $0.05 million for the six months ended June 30, 2020 and $0.20 million for the six months ended June 30, 2019. A decrease of $0.15 million was due to interest received on invested cash and cash equivalents.

Liquidity and Capital Resources

In February 2020, we completed an underwritten public offering, in which we sold 10,000,000 shares of common stock at a public offering price of $1.30 per share. The shares sold included 769,230 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. We received gross proceeds of approximately $13 million and net proceeds of approximately $11.9 million after deducting underwriting discounts and commissions. Our operations have also been financed from cash of $29.1 million from the consummation of the Merger in March 2019. As of June 30, 2020, we had $16.9 million of cash and cash equivalents.

On July 22, 2020, we filed a shelf registration statement, or the 2020 Shelf Registration Statement, with the SEC, for the issuance of common stock, preferred stock, warrants, rights, debt securities and units, which we refer to collectively as the Shelf Securities, up to an aggregate amount of $100 million. The 2020 Shelf Registration Statement was declared effective on July 31, 2020. On August 13, 2020, the Company sold 6,900,000 shares of its common stock at a public offering price of $2.75 per share pursuant to the 2020 Shelf Registration Statement, which includes 900,000 shares issued upon the exercise by the underwriter of its option to purchase additional shares at the public offering price, minus underwriting discounts and commissions. We received gross proceeds of approximately $19.0 million and net proceeds of approximately $17.1 million, after deducting underwriting discounts and offering expenses. Approximately $81,000,000 of Shelf Securities remain available for future sale under the 2020 Shelf Registration Statement.

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 June 30, 2020 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 June 30, 2020, 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):

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (7,268)	$ (8,226)
Net cash provided by investing activities	–	29,106
Net cash provided by financing activities	12,040	750
Net increase in cash and cash equivalents	$ 4,772	$ 21,630

Net Cash Used in Operating Activities

Net cash used in operating activities was $7.3 million and $8.2 million for the six months ended June 30, 2020 and 2019, respectively. The decrease in cash used in operating activities of $0.9 million was primarily due to a halt in expenses related to progress and performance of the PDS0101 in combination with KEYTRUDA® in first-line treatment of recurrent/metastatic head and neck cancer clinical trial due to the COVID 19 pandemic, resulting in less utilization of cash for expenses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2019 relates entirely to cash received in the Merger.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 was due to the receipt of net proceeds from the issuance of common stock of $12.0 million.

Net cash provided by financing activities for the six months ended June 30, 2019 was primarily due to the receipt of net proceeds of $0.8 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 product 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 to 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 evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Quarterly Report. Our budgeted cash requirements in 2020 and beyond include expenses related to continuing development and clinical studies. We believe that our existing cash and cash equivalents as of June 30, 2020 are sufficient to continue operations and research and development programs for at least the next 12 months from the date of this Quarterly Report. Until we can generate significant cash from our operations, we expect to continue to fund our operations with available financial resources. These financial resources may not be adequate to sustain our operations.

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 effects of health epidemics, pandemics, or outbreaks of infectious diseases, including the recent COVID-19 pandemic, on our business operations, financial condition, results of operations and cash flows;
- 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.

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.

As a result of the impairment and write-off of the IPR&D asset at year end, the only critical accounting policy and estimate we have for the three months ended June 30, 2020 is related to the stock- based compensation.

Impact of the CARES Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted and signed into law, and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act, among other things, includes changes to the tax provisions that benefits business entities and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act, including, permitting net operating losses, or NOLs, carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act provides other reliefs and stimulus measures. We have evaluated the impact of the CARES Act, and do not expect that any provision of the CARES Act would result in a material cash benefit to us or have a material impact on our financial statements or internal controls over financial reporting.

Impact of COVID-19 on our Business

In December 2019, a novel coronavirus known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease, known as COVID-19, that has now spread globally. On January 30, 2020, the World Health Organization (WHO) declared COVID-19 a pandemic, which we refer to herein as the COVID-19 Pandemic. The Secretary of Health and Human Services declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the COVID-19 Pandemic.

Operations and Liquidity

The full impact of the COVID-19 Pandemic is unknown and rapidly evolving. While the potential economic impact brought by and over the duration of the COVID-19 Pandemic may be difficult to assess or predict, the COVID-19 Pandemic has resulted in significant disruption of global financial markets, which could in the future negatively affect our liquidity. In addition, a recession or market volatility resulting from the COVID-19 Pandemic could affect our business. We have taken proactive, aggressive action throughout the COVID-19 Pandemic to protect the health and safety of our employees, and expect to continue to implement these measures until we determine that the COVID-19 Pandemic is adequately contained for purposes of our business. We may take further actions as government authorities require or recommend or as we determine to be in the best interests of our employees. Given the nature and type of our short-term investments, we do not believe that the COVID-19 Pandemic will have a material impact on our current investment liquidity.

Delay of Clinical Trials

To date, two of the three currently planned PDS0101 clinical trials have been delayed, specifically as a result of the adverse impact the COVID-19 Pandemic has had on clinical trial operations for cancer indications in the United States.

Outlook

Although there is uncertainty related to the anticipated impact of the recent COVID-19 Pandemic on our future results, we believe our current cash reserves, which includes approximately $17.1 million in net proceeds from our August 2020 public offering, leave us well-positioned to manage our business through this crisis as it continues to unfold. However, the impacts of the COVID-19 Pandemic are broad-reaching and continuing and the financial impacts associated with the COVID-19 Pandemic are still uncertain.

The COVID-19 Pandemic is ongoing, and its dynamic nature, including uncertainties relating to the ultimate geographic spread of the virus, the severity of the disease, the duration of the pandemic, and actions that would be taken by governmental authorities to contain the pandemic or to treat its impact, makes it difficult to forecast any effects on our results for the fiscal year ending December 31, 2020.

Despite the economic uncertainty resulting from the COVID-19 Pandemic, we intend to continue to focus on the development of our product candidates. We continue to monitor the rapidly evolving situation and guidance from international and domestic authorities, including federal, state and local public health authorities and may take additional actions based on their recommendations. In these circumstances, there may be developments outside our control requiring us to adjust our operating plan. As such, given the dynamic nature of this situation, we cannot reasonably estimate the impacts of COVID-19 on our financial condition, results of operations or cash flows in the future.

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.

JOBS Act

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Furthermore, we anticipate that we will no longer be an emerging growth company as of December 31, 2020.

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 June 30, 2020, we had cash equivalents of $16.9 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

Our management, with the participation of our Chief Executive Officer and Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, or DCPs, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. DCPs include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our DCPs, our Chief Executive Officer and Principal Accounting Officer concluded that, due to a previously reported material weakness, our internal control over financial reporting was not effective as of June 30, 2020. Specifically, we identified a material weakness in four components of internal control as defined by COSO 2013 (Control Environment, Risk Assessment, Control Activities and Information & Communication). These material weaknesses resulted in the immaterial error correction of the consolidated financial statements and related notes as of December 31, 2018 and for the year then ended and immaterial errors corrected within the consolidated financial statements as of and for the year then ended December 31, 2019.

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

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

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

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

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), or ICFR, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Remediation Efforts to Address Material Weakness

As previously described in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2019, we began implementing a remediation plan to address the material weaknesses mentioned above.

While we believe that we have improved our organizational capabilities, the material weaknesses remained unremediated as of June 30, 2020 and our remediation activities are continuing to take place in 2020. We continue to strengthen our internal control over financial reporting and we are committed to ensuring that such controls are designed and operating effectively.

The material weakness will not be considered remediated until the applicable controls are designed, implemented and operating for a sufficient period of time and management has concluded, that these controls are operating effectively

Changes in Internal Control over Financial Reporting

In addition to our identification and assessment of the material weakness described above, we are currently integrating our pre-Merger business into the pre-established internal control framework of Edge 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 2020. We have modified some of our internal control procedures due to the COVID-19 restrictions.

Edge was previously subject to the provisions of the Sarbanes-Oxley Act of 2002, as amended, whereas Private PDS 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 risks described below may not be the only ones relating to our company. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, financial conditions and future prospects and the trading price of our common stock could be harmed as a result of any of these risks. Investors should also refer to the other information contained or incorporated by reference in our Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 27, 2020, including our financial statements and related notes, and our other filings from time to time with the Securities and Exchange Commission or SEC.

The risk factors set forth below contain material changes from, or additions to, the risk factors previously disclosed and included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 27, 2020.

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 the three months ended June 30, 2020, we had an accumulated deficit of $35.9 million.

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

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

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

Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of PDS0101 or potentially discontinue operations. In July 2019, we entered into a common stock purchase agreement, or the Aspire Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, at our discretion, Aspire Capital is committed to purchase up to an aggregate of $20.0 million of shares of our common stock, or the Purchased Shares, over the 30-month term of the Aspire Purchase Agreement. We may sell an aggregate of 1,034,979 shares of our common stock (which represented 19.99% of the Company's outstanding shares of common stock on the date of the Aspire Purchase Agreement) without stockholder approval. We may sell additional shares of our common stock above the 19.99% limit provided that (i) we obtain stockholder approval or (ii) stockholder approval has not been obtained at any time the 1,034,979 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Aspire Purchase Agreement, is equal to or greater than $5.76, which was the consolidated closing bid price of our common stock on July 26, 2019. On July 29, 2019, we issued 100,654 shares of our common stock to Aspire Capital, as consideration for entering into the Aspire Purchase Agreement, which we refer to as the Commitment Shares. As of June 30, 2020, no Purchase Shares have been sold to Aspire Capital under the Aspire Purchase Agreement. Further, our use of the Aspire Purchase Agreement is subject to certain additional limitations set forth elsewhere in this report. As such, our ability to use the Aspire Purchase Agreement to raise additional capital is uncertain.

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 June 30, 2020, we had 13 employees and 5 consultants. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. Additionally, as part of our material weakness remediation plan, we intend to hire a new Chief Financial Officer and accounting and finance personnel as needed. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of PDS0101. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality

candidates and consultants than what it has to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop PDS0101 and our business will be limited.

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 June 30, 2020, we had 15,361,619 shares of common stock outstanding. Approximately 12,253,506 of such shares are freely tradable, without restriction, in the public market. Approximately 3,108,113 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 current executive officers and directors as a group beneficially own or control approximately 13% of the outstanding shares of our common stock as of June 30, 2020. 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 business operations, financial condition, results of operations and cash flows have been adversely affected and will likely continue to be adversely affected by the effects of health epidemics, pandemics, or outbreaks of infectious diseases, including the recent COVID-19 pandemic.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely.

For example, in December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and in March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. The COVID-19 pandemic began to have a material adverse impact on our results of operations in the quarter ended March 31, 2020, and we expect it to continue to adversely affect our business. In response to the COVID-19 outbreak, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, key vendors and partners. Our clinical development program timelines have been and continue to be negatively affected by COVID-19, as evidenced by the delay in the initiation of our planned Phase 2 study of PDS0101 in combination with KEYTRUDA® in first-line treatment of recurrent/metastatic head and neck cancer and initiation of the Phase 2 clinical study at The MD Anderson Cancer Center in combination with CRT. The evolving COVID-19 pandemic has also impacted the pace of enrollment in clinical trials and we may be affected by similar delays as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. In addition, the COVID-19 pandemic has affected and may continue to affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals.

As a result of the COVID-19 outbreak, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and "shelter in place" orders;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

Further, on March 25, 2020, the FDA issued Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic for Industry, Investigators, and Institutional Review Boards to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practices, and minimizing risks to trial integrity during the COVID-19 Pandemic, or the COVID-19 Guidelines. The policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services on January 31, 2020. We have implemented several procedures in accordance with the COVID-19 Guidelines to address patient safety and clinical trial conduct during the COVID-19 pandemic, including remote monitoring of patients through telemedical visits, remote monitoring of sites by our clinical trial monitors, remote data entry, and follow-up visits at sites other than the site where the patient was initially treated. Our implementation of the COVID-19 Guidelines and potential disruptions to patient follow up, site monitoring or the timely completion of our trials may have a negative effect on our ability to complete trials and associated regulatory filings.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets has reduced and may continue to reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects have had and may continue to have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely and a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. We will continue to monitor the COVID-19 situation closely.

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 June 30, 2020.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1	Consulting Agreement made as of June 23, 2020 by and between PDS Biotechnology Corporation and King Partners II (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K on June 24, 2020 and incorporated herein by reference).
31.1	Certification of Principal Executive and 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).
31.2	Certification of Principal Accounting 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 and 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).
32.2 *	Certification of Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

SIGNATURES

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

PDS Biotechnology Corporation

August 13, 2020

By: /s/ Frank Bedu-Addo
Frank Bedu-Addo
President and Chief Executive Officer

August 13, 2020

By: /s/ Michael King
Michael King
Interim Chief Financial Officer