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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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

For the transition period from _____ to _____

Commission file number 001-37568

PDS Biotechnology Corp oration

(Exact name of registrant as specified in its charter)

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

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

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

(Former name, former address and former fiscal year, if changed since last report)

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	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

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

The number of shares of the registrant's Common Stock, par value $0.00033 per share, outstanding as of November 7, 2023 was 31,107,763 .

PDS BIOTECHNOLOGY CORPORATION

FORM 10-Q FOR THE QUARTER ENDED September 30, 2023

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARY

Condensed Consolidated Balance Sheets

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54,251,387	$ 73,820,160
Prepaid expenses and other assets	2,587,025	2,660,230
Total current assets	56,838,412	76,480,390
Property and equipment, net	138,866	-
Financing lease right-of-use assets	210,543	374,888
Operating lease right-of-use asset	-	152,645
Total assets	$ 57,187,821	$ 77,007,923
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,366,564	$ 1,219,287
Accrued expenses	3,732,727	8,313,708
Financing lease obligation-short term	54,537	56,612
Operating lease obligation-short term	-	231,429
Total current liabilities	9,153,828	9,821,036
Noncurrent liabilities:		
Note payable, net of debt discount	23,412,764	23,020,844
Financing lease obligation-long term	137,401	164,013
Total liabilities:	$ 32,703,993	$ 33,005,893
STOCKHOLDERS' EQUITY		
Common stock, $ 0.00033 par value, 75,000,000 shares authorized at September 30, 2023 and December 31, 2022, 31,007,763 shares and 30,170,317 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	10,233	9,956
Additional paid-in capital	158,075,994	145,550,491
Accumulated deficit	(133,602,399)	(101,558,417)
Total stockholders' equity	24,483,828	44,002,030
Total liabilities and stockholders' equity	$ 57,187,821	$ 77,007,923

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARY

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development expenses	$ 6,448,528	$ 4,352,987	$ 20,297,066	$ 13,275,947
General and administrative expenses	4,071,158	2,926,209	12,341,207	9,575,122
Total operating expenses	10,519,686	7,279,196	32,638,273	22,851,069
Loss from operations	(10,519,686)	(7,279,196)	(32,638,273)	(22,851,069)
Interest income (expenses), net				
Interest income	739,404	252,073	2,219,399	332,318
Interest expense	(1,068,887)	(397,327)	(3,031,129)	(397,326)
Interest income (expenses), net	(329,483)	(145,254)	(811,730)	(65,008)
Loss before income taxes	(10,849,169)	(7,424,450)	(33,450,003)	(22,916,077)
Benefit for income taxes	-	-	1,406,021	1,198,905
Net loss and comprehensive loss	(10,849,169)	(7,424,450)	(32,043,982)	(21,717,172)
Per share information:				
Net loss per share, basic and diluted	$ (0.35)	$ (0.26)	$ (1.04)	$ (0.76)
Weighted average common shares outstanding, basic, and diluted	30,910,520	28,458,688	30,715,458	28,452,997

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARY

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

	Common Stock				
	Shares Issued	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Equity
January 1, 2022	28,448,612	$ 9,387	$ 123,904,602	$ (60,703,562)	$ 63,210,427
Stock based compensation expense	-	-	1,128,973	-	1,128,973
Issuances of common stock, from exercise of stock options	2,282	1	7,487	-	7,488
Net loss	-	-	-	(8,473,522)	(8,473,522)
Balance - March 31, 2022	28,450,894	$ 9,388	$ 125,041,062	$ (69,177,084)	$ 55,873,366
Stock based compensation expense	-	-	1,348,601	-	1,348,601
Issuances of common stock, from exercise of stock options	7,794	3	22,426	-	22,429
Net loss	-	-	-	(5,819,200)	(5,819,200)
Balance - June 30, 2022	28,458,688	$ 9,391	$ 126,412,089	$ (74,996,284)	$ 51,425,196
Stock based compensation expense	-	-	1,344,349	-	1,344,349
Issuances of warrants	-	-	1,713,714	-	1,713,714
Net loss	-	-	-	(7,424,450)	(7,424,450)
Balance - September 30, 2022	28,458,688	$ 9,391	$ 129,470,179	$ (82,420,734)	$ 47,058,836

	Common Stock				
	Shares Issued	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Equity
January 1, 2023	30,170,317	$ 9,956	$ 145,550,491	$(101,558,417)	$ 44,002,030
Stock based compensation expense	-	-	2,080,319	-	2,080,319
Issuances of common stock from the Sales Agreement, net	553,293	183	4,588,339	-	4,588,522
Net loss	-	-	-	(9,659,918)	(9,659,918)
Balance - March 31, 2023	30,723,610	$ 10,139	$ 152,219,149	$(111,218,335)	$ 41,010,953
Stock based compensation expense	-	-	2,105,538	-	2,105,538
Issuances of common stock, from exercise of stock options	1,409	1	8,848	-	8,849
Issuance of common stock for consulting agreement	100,000	33	609,967	-	610,000
Issuances of common stock from the Sales Agreement, net	43,169	14	243,729	-	243,743
Net loss	-	-	-	(11,534,895)	(11,534,895)
Balance - June 30, 2023	30,868,188	$ 10,187	$ 155,187,231	$(122,753,230)	$ 32,444,188
Stock based compensation expense	-	-	2,073,607	-	2,073,607
Issuances of common stock from the Sales Agreement, net	139,575	46	815,156	-	815,202
Net loss	-	-	-	(10,849,169)	(10,849,169)
Balance - September 30, 2023	31,007,763	$ 10,233	$ 158,075,994	$(133,602,399)	$ 24,483,828

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARY

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (32,043,982)	$ (21,717,172)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,259,464	3,821,923
Issuance of shares in consulting agreement	610,000	-
Amortization of debt discount	391,920	72,722
Depreciation expense	12,624	86
Operating lease expense	160,685	180,772
Finance lease depreciation expense	30,297	37,417
Changes in assets and liabilities:		
Prepaid expenses and other assets	73,205	(1,171,337)
Finance lease right-of-use asset	-	(306,487)
Accounts payable	4,147,277	727,987
Accrued expenses	(4,580,981)	240,799
Finance lease liabilities	-	138,402
Operating lease liabilities	(239,469)	(205,885)
Net cash used in operating activities	(25,178,960)	(18,180,773)
Cash flows from financing activities:		
Proceeds from issuance of note payable	-	25,000,000
Payment for debt issuance costs	-	(449,329)
Proceeds from exercise of stock options	8,849	29,917
Payments of finance lease obligations	(46,129)	-
Proceeds from issuance of common stock, net of issuance costs	5,647,467	-
Net cash provided by financing activities	5,610,187	24,580,588
Net increase in cash and cash equivalents	(19,568,773)	6,399,815
Cash and cash equivalents at beginning of period	73,820,160	65,242,622
Cash and cash equivalents at the end of period	$ 54,251,387	$ 71,642,437
Supplemental information of cash and non-cash transactions:		
Cash paid for interest	$ 3,031,129	$ 62,500
Fair value of warrants issued in connection with debt	$ -	$ 1,713,741

See accompanying notes to the condensed consolidated financial statements.

PDS BIOTECHNOLOGY CORPORATION AND SUBSIDIARY
Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1 – Nature of Operations

PDS Biotechnology Corporation, a Delaware corporation (the "Company" or "PDS Biotech"), is a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer and infectious disease immunotherapies based on its Versamune®, Versamune® plus our IL12 fused antibody-drug conjugate (ADC) PDS01ADC (formerly PDS0301/M9241) and Infectimune® T cell-activating platforms and PDS01ADC tumor targeting immunocytokine. The Company believes its targeted immunotherapies have potential to overcome the limitations of current immunotherapy approaches through the activation of the right type, quantity and potency of T cells. Versamune, and Versamune plus PDS01ADC is for treatments in oncology and Infectimune, for treatments in infectious disease. When paired with an antigen, which is a disease-related protein that is recognizable by the immune system, Versamune and Infectimune have both been shown to induce, *in vivo,* large quantities of high-quality, highly potent polyfunctional CD4 helper and CD8 killer T cells, a specific sub-type of T cell that is more effective at killing infected or target cells. Infectimune is also designed to promote the induction of disease-specific neutralizing antibodies. PDS01ADC is an investigational tumor targeting IL-12 that enhances the proliferation, potency and longevity of T cells in the tumor microenvironment. Versamune plus PDS01ADC enhances the proliferation, potency and longevity of antigen specific multifunctional CD8 T cells in the tumor microenvironment and works synergistically to overcome tumor immune suppression.

The Company's immuno-oncology clinical candidates are of potential interest for use as a component of combination clinical candidates (for example, in combination with other leading technologies such as immune checkpoint inhibitors) to provide more effective treatments across a range of advanced cancers. The Company is also evaluating our immunotherapies as monotherapies in early-stage disease. PDS Biotech is developing targeted clinical candidates to treat several cancers including Human Papillomavirus (HPV)-positive cancers, melanoma, colorectal, lung, breast and prostate cancers. The Company's infectious disease candidates are of potential interest for use in universal influenza vaccines.

Note 2 – Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at September 30, 2023, the statements of operations and comprehensive loss and changes in stockholders' equity and cash flows for the three and nine months ended September 30, 2023 and 2022 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 nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The balance sheet as of December 31, 2022 included herein was derived from the audited 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, 2022, filed by the Company with the SEC in its Annual Report on Form 10-K on March 28, 2023.

(B) Use of estimates:

The preparation of condensed 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. The most significant estimate relates to the fair value of securities underlying stock-based compensation.

(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 clinical candidates, the ability to preserve its cash resources, the Company's review of strategic alternatives, the ability to add clinical candidates to its pipeline, the Company's intellectual property, the ability to efficiently and effectively conduct its clinical trials, 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 ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, the ability to raise capital, and the effects of health epidemics, pandemics, or outbreaks of infectious diseases.

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

(D) Cash equivalents and concentration of cash balance:

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

(E) Research and development:

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in the Company's research and development projects as well as fees paid to consultants and 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 trial site activations or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

(F) Patent costs:

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

(G) Stock-based compensation:

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, directors and non-employees to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values. In order to determine the fair value of stock options on the date of grant, the Company uses the Black-Scholes option-pricing model. Inherent in this model are assumptions related to expected stock-price volatility, option term, risk-free interest rate and dividend yield. The Company expenses the fair value of its stock-based compensation awards to employees and directors on a straight-line basis over the requisite service period, which is generally the vesting period. The Company recognizes forfeitures as they occur.

(H) Net loss per common share:

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the common shares underlying the stock options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted average shares outstanding used to calculate both basic and diluted loss per common share is the same.

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

	As of September 30,	
	2023	**2022**
Stock options to purchase Common Stock	5,383,902	4,370,846
Warrants to purchase Common Stock	506,229	506,229
Total	5,890,131	4,877,075

(I) Income taxes:

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

(J) Fair value of financial instruments:

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

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

- Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

- Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies.

- Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

(K) Leases:

The Company determines if an arrangement is a lease at inception and recognizes the lease in accordance with ASC 842, Leases (“ASC 842”). Both financing and operating leases are included in right-of-use (“ROU”) assets, lease obligation-short term and lease obligation-long term in the Company’s consolidated balance sheets. ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. The ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term. The Company determines the portion of the lease liability that is current as the difference between the calculated lease liability at the end of the current period and the lease liability that is projected 12 months from the current period.

Note 3 – Liquidity

As of September 30, 2023, the Company had $ 54.3 million of cash and cash equivalents. 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. Since inception, the Company has experienced net losses and negative cash flows from operations each fiscal year. The Company has no revenues and expects to continue to incur operating losses for the foreseeable future and may never become profitable.

The Company funds its operations through equity and/or debt financings such as the following:

In April 2022, the Company received approximately $ 1.2 million from the net sale of tax benefits to an unrelated, profitable New Jersey corporation pursuant to the Company’s participation in the New Jersey Technology Business Tax Certificate Transfer NOL program for tax year 2020.

In August 2022, the Company filed a shelf registration statement, or the 2022 Shelf Registration Statement, with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities, and units, up to an aggregate amount of $ 150 million, $ 50 million of which covers the offer, issuance and sale by the Company of its common stock under the Sales Agreement (as discussed below). The 2022 Shelf Registration Statement was declared effective on September 2, 2022.

In August 2022, the Company entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with B. Riley Securities, Inc. and BTIG, LLC, each an Agent and collectively the Agents, with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $ 50 million, or the Placement Shares, through or to the Agents, as sales agents or principals. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Agents may sell the Placement Shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, as amended, including, without limitation, sales made through The Nasdaq Capital Market or on any other existing trading market for the Company's common stock. The Agents will use commercially reasonable efforts to sell the Placement Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the Agents a commission equal to three percent (3 %) of the gross sales proceeds of any Placement Shares sold through the Agents under the Sales Agreement, and the Company has also provided the Agents with customary indemnification and contribution rights. The Company is not obligated to make any sales of its common stock under the Sales Agreement. The offering of Placement Shares pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Placement Shares subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. For the year ended December 31, 2022, the Company sold 1,238,491 shares of common stock with a net value of $ 9.9 million pursuant to the Sales Agreement. During the three and nine months ended September 30, 2023, the Company sold 139,575 and 736,037 shares, respectively, of its common stock with a net value of $ 0.8 million and $ 5.6 million, respectively, pursuant to the Sales Agreement.

In August 2022, the Company entered into a venture loan and security agreement, or the Loan and Security Agreement, with Horizon Technology Finance Corporation, as lender and collateral agent for itself and the other lenders. The Loan and Security Agreement provides for the following 6 separate and independent term loans: (a) a term loan in the amount of $ 7,500,000 , or Loan A, (b) a term loan in the amount of $ 10,000,000 , or Loan B, (c) a term loan in the amount of $ 3,750,000 , or Loan C, (d) a term loan in the amount of $ 3,750,000 , or Loan D, (e) a term loan in the amount of $ 5,000,000 , or Loan E, and (f) a term loan in the amount of $ 5,000,000 , or Loan F, (with each of Loan A, Loan B, Loan C, Loan D, Loan E, and Loan F, individually a Loan and, collectively, the Loans). Loan A, Loan B, Loan C , and Loan D were delivered to the Company on August 24, 2022. Loan E and Loan F were uncommitted Loans that could have been advanced by the lenders upon the parties agreement prior to July 31, 2023 upon the satisfaction of certain conditions. At this time the option to advance Loan E and Loan F has expired and Loan E and Loan F are no longer available to the Company under the Loan and Security Agreement . The Company may only use the proceeds of the Loans for working capital or general corporate purposes. Each Loan matures on the 48 -month anniversary following the applicable funding date unless accelerated pursuant to certain events of default. Payments on the principal balance begin on October 1, 2024 and are paid monthly in the succeeding 24 months. The principal balance of each Loan bears a floating interest. The interest rate is calculated initially and, thereafter, each calendar month as the sum of (a) the per annum rate of interest from time to time published in The Wall Street Journal as contemplated by the Loan and Security Agreement, or any successor publication thereto, as the "prime rate" then in effect, plus (b) 5.75 %; provided that, in the event such rate of interest is less than 4.00 %, such rate shall be deemed to be 4.00 % for purposes of calculating the interest rate. Interest is payable on a monthly basis based on each Loan principal amount outstanding the preceding month. The Company, at its option upon at least ten (10) business days' written notice to the lenders, may prepay all (and not less than all) of the outstanding Loan by simultaneously paying to each lender an amount equal to (i) any accrued and unpaid interest on the outstanding principal balance of the Loans; plus (ii) an amount equal to (A) if such Loan is prepaid on or before the Loan Amortization Date (as defined in the Loan and Security Agreement) applicable to such Loan, 3 % of the then outstanding principal balance of such Loan, (B) if such Loan is prepaid after the Loan Amortization Date applicable to such Loan, but on or before the date that is 12 months after such Loan Amortization Date, 2 % of the then outstanding principal balance of such Loan, or (C) if such Loan is prepaid more than 12 months after the Loan Amortization Date but prior to the stated maturity date applicable to such Loan, 1 % of the then outstanding principal balance of such Loan; plus (iii) the outstanding principal balance of such Loan; plus (iv) all other sums, if any, that shall have become due and payable thereunder. No prepayment premium will be applied to any outstanding balance of any Loan paid on the stated maturity date.

The Loan and Security Agreement contains customary representations, warranties and covenants, including covenants by the Company limiting additional indebtedness, liens, including on intellectual property, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates, and fundamental changes.

In April 2023, the Company received approximately $ 1.4 million from the net sale of tax benefits to an unrelated, profitable New Jersey corporation pursuant to the Company's participation in the New Jersey Technology Business Tax Certificate Transfer NOL program for tax year 2021.

Going Concern

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 after the filing of this Quarterly Report on Form 10-Q in accordance with ASC 205-40. Since inception, the Company has experienced net losses and negative cash flows from operations each fiscal year. The Company has no revenues and expects to continue to incur operating losses for the foreseeable future and may never become profitable.

The Company's budgeted cash requirements in 2023 and beyond include expenses related to continuing development and clinical trials. The Company plans to execute its operating plan by obtaining additional capital, principally through entering into collaborations, strategic alliances, or license agreements with third parties and/or additional public or private debt and equity financing. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or its existing shareholders or in the amounts required. The Company may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to the Company's stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict its operations. If the Company is unsuccessful in securing sufficient financing, it may need to delay, reduce, or eliminate its research and development programs, which could adversely affect its business prospects, grant rights to third parties to develop and market immunotherapies that the Company would otherwise prefer to develop and market itself or cease operations. Any of these actions could harm its 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.

As a result of these uncertainties, and as its plans are outside of management's control, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these unaudited condensed consolidated financial statements. The unaudited condensed consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern.

Note 4 – Fair Value of Financial Instruments

There were no transfers among Levels 1, 2, or 3 during the three and nine months ended September 30, 2023 or 2022.

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets (Level 1)	Quoted Prices in Inactive Markets (Level 2)	Significant Unobservable Inputs (Level 3)
As of September 30, 2023: (unaudited)				
Cash and cash equivalents	$ 54,251,387	$ 54,251,387	$ –	$ –
As of December 31, 2022				
Cash and cash equivalents	$ 73,820,160	$ 73,820,160	$ –	$ –

The carrying value of the Note Payable approximated its fair value at September 30, 2023 due to its variable rate.

Note 5 – Leases

Operating Lease:

Effective March 5, 2020, the Company entered into a sublease for approximately 11,200 square feet of office space located at 25B Vreeland Road, Suite 300, 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. As of August 31, 2023 the lease term has expired and was not renewed. Upon inception of the sublease, 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.

Supplemental cash flow information related to operating leases is as follows:

	As of September 30,	
	2023	2022
Cash paid for operating lease liabilities	$ 239,469	$ 205,885

Financing Lease:

The Company has financed certain laboratory equipment as follows:

	As of September 30,	
	2023	2022
Cash paid for finance lease liabilities	$ 60,684	$ 306,487

Maturity of the Company's financing lease liability is as follows:

Year ended September 30,	
2023	$ 17,464
2024	$ 69,850
2025	$ 69,850
2026	$ 40,108
2027 and after	$ 26,724
Total future minimum lease payments	223,996
Less imputed interest	(32,058)
Remaining lease liability	$ 191,938

The Company entered into four financing leases for laboratory equipment with a total cost of $ 251,959 with four to five-year terms and a capitalized interest rate of 9.15 %. Each of the lease agreements include a bargain purchase option to acquire the equipment at the end of the lease term. The aggregate monthly payments are approximately $ 6 ,000. In the nine months ended September 30, 2023, the Company exercised a bargain purchase option, which resulted in recognition of property and equipment of $ 151,490 .

Note 6 – Accrued Expenses

Accrued expenses and other liabilities consist of the following:

	As of September 30, 2023	As of December 31, 2022
Accrued research and development	$ 79,910	$ 5,645,737
Accrued professional fees	1,570,401	550,259
Accrued compensation	1,785,173	1,837,330
Accrued interest on debt	296,875	280,382
Accrued rent	368	-
Total	$ 3,732,727	$ 8,313,708

Note 7 – Stock-Based Compensation

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

As previously disclosed, on December 8, 2020, the Board of Directors of the Company adopted, subject to stockholder approval, the Second Amended and Restated PDS Biotechnology Corporation 2014 Equity Inventive Plan (the "Restated Plan"), which amended and restated the Amended and Restated PDS Biotechnology Corporation 2014 Equity Incentive Plan (the "Current Plan"). At the annual meeting of stockholders on June 17, 2021 the stockholders voted to approve the Restated Plan at the Annual Meeting. The Restated Plan is identical to the Current Plan in all material respects, except as follows: (a) the number of shares of Common Stock authorized for issuance under the Restated Plan will increase from 826,292 shares to 3,339,243 shares, plus the total number of shares that remained available for issuance, that are not covered by outstanding awards issued under the Current Plan, immediately prior to December 8, 2020; and (b) the Restated Plan will terminate on December 7, 2030, unless earlier terminated. On July 14, 2023, the Company's stockholders approved an amendment to the Current Plan increasing the number of shares of common stock for issuance from 4,165,535 to 6,565,535 shares. As of September 30, 2023, there were 119,013 shares available for grant under the Restated Plan.

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 (i) Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock, (iv) Preferred Stock, (v) Stock Reload Options and/or (vi) Other Stock-Based Awards. As of September 30, 2023, there were 190,799 shares available for grant under the Restated Plan.

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 period. Unless terminated by the Board, the Plans shall continue to remain effective for a term of ten years or until such time as no further awards may be granted and all awards granted under the Plans are no longer outstanding.

On June 17, 2019, the Board adopted the 2019 Inducement Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of non-qualified stock options. The 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. On December 8, 2020, the Company amended the Inducement Plan solely to increase the total number of shares of Common Stock reserved for issuance under the Inducement Plan from 200,000 shares to 500,000 shares. On May 17, 2022, the Company further amended the Inducement Plan solely to increase the total number of shares of Common Stock reserved for issuance under the Inducement Plan from 500,000 shares to 1,100,000 shares. The 2019 Inducement Plan is 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 September 30, 2023, there were 185,315 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Stock-Based Compensation				
Research and development	$ 782,249	$ 493,083	$ 2,389,561	$ 1,349,664
General and administrative	1,291,358	851,267	3,869,903	2,472,259
Total	$ 2,073,607	$ 1,344,350	$ 6,259,464	$ 3,821,923

There were 59,500 and 1,214,000 of options granted during the three and nine month periods ended September 30, 2023, respectively and 87,000 and 1,526,005 of options granted during the three and nine month period ended September 30, 2022, respectively. The fair value of options granted during the three and nine months ended September 30, 2023 and 2022 was estimated using the Black-Scholes option valuation model utilizing the following assumptions.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	Weighted Average	Weighted Average	Weighted Average	Weighted Average
	(unaudited)		(unaudited)	
Volatility	150.26%	101.43%	142.47%	99.56%
Risk-Free Interest Rate	3.92%	3.03%	4.04%	1.70%
Expected Term in Years	5.59	6.08	6.06	6.41
Dividend Rate	–	–	–	–
Fair Value of Option on Grant Date	$ 4.77	$ 2.58	$ 10.35	$ 4.80

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, 2022	4,171,311	$ 5.56	7.89	$ 32,779,920
Granted	1,214,000	11.14		
Exercised	(1,409)	-		
Forfeited and expired	-	-		
Options outstanding at September 30, 2023	5,383,902	$ 6.82	7.63	$ 4,685,828
Vested and expected to vest at September 30, 2023	5,383,902	$ 6.82	7.63	$ 4,685,828
Exercisable at September 30, 2023	2,722,797	$ 5.72	6.67	$ 3,225,309

At September 30, 2023 there was approximately $ 18,568,032 of unamortized stock option compensation expense, which is expected to be recognized over a remaining average vesting period of 2.51 years.

The Company entered into an agreement with DC Consulting for certain consulting services and issued 100,000 shares in connection with the agreement.

Note 8 – 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 2023 and there will be no current income tax expense. Additionally, there was a full valuation allowance against the net deferred tax assets as of September 30, 2023 and December 31, 2022. As such, the Company recorded no income tax benefit due to realization uncertainties.

The Company's U.S. statutory rate is 21 %. The primary factor impacting the effective tax rate for the three and nine months ended September 30, 2023 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 positions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of September 30, 2023, 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 no t have any unrecognized tax benefits and has no t accrued any interest or penalties for the three and nine months ended September 30, 2023 and for the year ended December 31, 2022.

In accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allows certain high technology and biotechnology companies to sell unused NOL carryforwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carryforwards, resulting in the recognition of $ 1.4 million and $ 1.2 million of income tax benefit, net of transaction costs in the nine months ended September 30, 2023 and 2022, respectively.

Note 9 – Commitments and Contingencies

Rent

For month-to-month arrangements not impacted by the adoption of ASC 842, rent for the three and nine months ended September 30, 2023 was $ 106,171 and $ 359,373 respectively, compared to the three and nine months ended September 30, 2022 of $ 55,500 and $ 165,500 .

Exclusive License Agreement

In January 2023, we entered into an exclusive global license agreement with Merck KGaA, Darmstadt, Germany for the tumor targeting IL 12 fused antibody drug conjugate, M9241 (the "Merck KGaA License Agreement"). Pursuant to the Merck KGaA License Agreement, the Company agreed to make (i) development and first commercial sale milestone payments totaling up to $ 11 million upon the achievement of certain milestones, including the dosing of the fifth patient in a Phase 3 trial of the clinical candidate and first commercial sale of the product for a first and second indication in a major market, and (ii) up to $ 105 million upon achieving certain aggregate sales levels of the product.

The Company also agreed to pay Merck KGaA, Darmstadt, Germany a royalty of 10 % on aggregate net sales of product as specified in the Merck KGaA License Agreement on a product-by-product and country-by-country basis until the later of: (i) ten years after the first commercial sale of a product in a given country; and (ii) the expiration or invalidation of the licensed patents covering the compound or product in such country. The royalty rate is subject to reduction in that event that a product is not covered by a valid patent claim, a biosimilar to the compound or the product comes on the market in a particular country, or if the Company obtains a license to any intellectual property owned or controlled by a third-party, but for which such license would be infringed by making, using or selling the compound.

Legal Proceedings

The Company is currently not a party to, and the Company's property is not currently the subject of, any material pending legal proceedings. The Company may be involved, from time to time, in legal proceedings and claims arising in the ordinary course of business. Such matters are subject to many uncertainties and outcomes are not predictable with assurance.

Note 10 – Venture Loan and Security Agreement

In August 2022, the Company entered into a Venture Loan and Security Agreement (the "Loan and Security Agreement") with Horizon Technology Finance Corporation, as a lender and collateral agent for itself and the other Lenders (in such capacity, the "Collateral Agent"), and the other persons party thereto from time to time as lenders ("Lenders").

Term loan Amounts. The Loan and Security Agreement provides for the following six (6) separate and independent term loans: (a) a term loan in the amount of $ 7,500,000 ("Loan A"), (b) a term loan in the amount of $ 10,000,000 ("Loan B"), (c) a term loan in the amount of $ 3,750,000 ("Loan C"), (d) a term loan in the amount of $ 3,750,000 ("Loan D"), (e) a term loan in the amount of $ 5,000,000 ("Loan E"), and (f) a term loan in the amount of $ 5,000,000 ("Loan F") (with each of Loan A, Loan B, Loan C, Loan D, Loan E, and Loan F, individually a "Loan" and, collectively, the "Loans"). Loan A, Loan B, Loan C, and Loan D were delivered to the Company on August 24, 2022. Loan E and Loan F were uncommitted Loans that could have been advanced by the Lenders upon the parties agreement prior to July 31, 2023 upon the satisfaction by the Company of certain agreed upon conditions. At this time the option has expired and Loan E and Loan F are no longer available to the Company under the Loan and Security Agreement . The Company may only use the proceeds of the Loans for working capital or general corporate purposes.

Maturity. Each Loan matures on the 4 8 month anniversary following the applicable date on which a Loan is made to or on account of the Company under the Loan and Security Agreement (the "Maturity Date") unless accelerated pursuant to agreed upon events of default. All amounts outstanding under each Loan will be due and payable upon the earlier of the Maturity Date or the acceleration of the loans and commitments upon an event of default.

Interest Rate. The principal balance of each Loan bears a floating interest. The interest rate is calculated initially and, thereafter, each calendar month as the sum of (a) the per annum rate of interest from time to time published in The Wall Street Journal as contemplated by the Loan and Security Agreement, or any successor publication thereto, as the “prime rate” then in effect, plus (b) 5.75 %; provided that, in the event such rate of interest is less than 4.00 %, such rate shall be deemed to be 4.00 % for purposes of calculating the interest rate. Interest is payable on a monthly basis based on each Loan principal amount outstanding the preceding month.

Amortization. Each Loan shall commence amortization upon the date set forth on the promissory note executed in connection with the respective Loan, upon which the Company is required to commence making equal payments of principal plus accrued interest on the outstanding principal amount of the respective Loan (the “Loan Amortization Date”), and continuing thereafter on the first business day of each calendar month through the Maturity Date.

Prepayment Premium. The Company may, at its option upon at least ten (10) business days’ written notice to the Lenders, prepay all (and not less than all) of the outstanding Loan by simultaneously paying to each Lender an amount equal to (i) any accrued and unpaid interest on the outstanding principal balance of the Loans; plus (ii) an amount equal to (A) if such Loan is prepaid on or before the Loan Amortization Date applicable to such Loan, three percent (3 %) of the then outstanding principal balance of such Loan, (B) if such Loan is prepaid after the Loan Amortization Date applicable to such Loan, but on or before the date that is twelve (12) months after such Loan Amortization Date, two percent (2 %) of the then outstanding principal balance of such Loan, or (C) if such Loan is prepaid more than twelve (12) months after the Loan Amortization Date but prior to the stated Maturity Date applicable to such Loan, one percent (1 %) of the then outstanding principal balance of such Loan; *plus* (iii) the outstanding principal balance of such Loan; *plus* (iv) all other sums, if any, that shall have become due and payable hereunder. No prepayment premium will be applied to any outstanding balance of any Loan paid on the stated Maturity Date.

Security. The Company’s obligations are secured by a security interest in all of the assets of the Company, subject to limited exceptions and excluding the Company’s intellectual property.

Covenants; Representations and Warranties; Other Provisions. The Loan and Security Agreement contains customary representations, warranties and covenants, including covenants by the Company limiting additional indebtedness, liens, including on intellectual property, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates, and fundamental changes.

Default Provisions. The Loan and Security Agreement provides for events of default customary for term loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, and bankruptcy by and/or of the Company.

Warrant and Debt Discount. In connection with the Loan and Security Agreement, the Company issued Horizon Technology Finance Corporation and Powerscourt Investments XXV, LP warrants to purchase an aggregate total of 381,625 shares of the Company’s common stock at an initial exercise price of $ 3.6685 per share. Each warrant is classified as equity and is exercisable at any time for a period beginning on the date of grant and ending on the earlier of (A) 10 years from the date of grant, and (B) the closing of (A) (i) the sale, lease, exchange, conveyance or other disposition of all or substantially all of the Company’s property or business, or (ii) its merger into or consolidation with any other corporation (other than a wholly-owned subsidiary of the Company), or any transaction (including a merger or other reorganization) or series of related transactions, in which more than 50 % of the voting power of the Company is disposed of, in each case, for cash or for marketable securities meeting certain requirements as described in the applicable warrants. The key assumptions used in the Black-Scholes option pricing model were (i) expected term of 10 years, (ii) a risk-free rate of 3.11 %, (iii) expected volatility of 93.8 %, (iv) and no estimated dividend yield. In addition, the Company incurred third party and lender fees of $ 449,329 for the nine months ended September 30, 2022. These proceeds were allocated on a basis that approximates the relative fair value method. The fair value of the warrant and fees incurred were recorded as a debt discount and are being recognized as interest expense over the life of the Loan and Security Agreement using the effective interest method. The unamortized debt discount was $ 2,524,736 as of September 30, 2023. The Company recognized interest expense of $ 1,064,300 and $ 3,016,572 for the three and nine months ended September 30, 2023 and $ 158,397 and $ 391,920 was related to the amortization of the debt discount for the three and nine months ended September 30, 2023.

Note 11 – Retirement Plan

The Company has a 401(k) defined contribution plan for the benefit for all employees and permits voluntary contributions by employees subject to IRS-imposed limitations. The 401(k) employer contributions were $ 32,861 and $ 164,631 for the three and nine months ended September 30, 2023, respectively, compared to the three and nine months ended September 30, 2022 of $ 31,515 and $ 119,232 respectively.

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, 2022 on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 28, 2023.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) concerning the Company and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the Company's management, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," "forecast," "guidance", "outlook" and other similar expressions among others. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation:

- the Company's ability to protect its intellectual property rights;
- the Company's anticipated capital requirements, including the Company's anticipated cash runway and the Company's current expectations regarding its plans for future equity financings;
- the Company's dependence on additional financing to fund its operations and complete the development and commercialization of its clinical candidates, and the risks that raising such additional capital may restrict the Company's operations or require the Company to relinquish rights to the Company's technologies or clinical candidates;
- the Company's limited operating history in the Company's current line of business, which makes it difficult to evaluate the Company's prospects, the Company's business plan or the likelihood of the Company's successful implementation of such business plan;
- the timing for the Company or its partners to initiate the planned clinical trials for PDS0101, PDS0103, PDS0203 and other Versamune and Infectimune based clinical candidates and the future success of such trials;
- the successful implementation of the Company's research and development programs and collaborations, including any collaboration trials concerning the Company's Versamune and Infectimune based clinical candidates and the Company's interpretation of the results and findings of such programs and collaborations and whether such results are sufficient to support the future success of the Company's clinical candidates;
- the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current clinical candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of the Company's ongoing clinical trials;
- expectations for the clinical and preclinical development, manufacturing, regulatory approval, and commercialization of our clinical candidates;
- any Company statements about its understanding of clinical candidates' mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs and any collaboration trials; the acceptance by the market of the Company's clinical candidates, if approved;
- the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, the Company's clinical candidates; and
- other factors, including legislative, regulatory, political and economic developments not within the Company's control, including unforeseen circumstances or other disruptions to normal business operations arising from or related to those listed under Part II, Item 1A. Risk Factors.

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

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

Company Overview

We are a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer and infectious disease immunotherapies based on our Versamune®, Versamune® plus IL12 fused anti-body drug conjugate (ADC) PDS01ADC (formerly PDS0301/M9241) and Infectimune ® T cell-activating platforms and PDS01ADC tumor targeting immunocytokine. We believe our targeted immunotherapies have the potential to overcome the limitations of current immunotherapy approaches through the activation of the right type, quantity and potency of T cells. Versamune, and Versamune plus PDS01ADC are utilized for treatments in oncology and Infectimune, for treatments in infectious disease. When paired with an antigen, which is a disease-related protein that is recognizable by the immune system, Versamune and Infectimune have both been shown to induce, *in vivo,* large quantities of high-quality, highly potent polyfunctional CD4 helper and CD8 killer T cells, a specific sub-type of T cell that is more effective at killing infected or target cells. Infectimune is also designed to promote the induction of disease-specific neutralizing antibodies. PDS01ADC is an investigational tumor targeting IL-12 that enhances the proliferation, potency and longevity of T cells in the tumor microenvironment. Versamune plus PDS01ADC enhances the proliferation, potency and longevity of antigen specific multifunctional CD8 T cells in the tumor microenvironment and works synergistically to overcome tumor immune suppression.

Recent Developments

In December 2022, we executed an exclusive global license agreement with Merck KGaA, Darmstadt, Germany for the tumor targeting IL12 fused antibody drug conjugate, M9241, which joined our pipeline as PDS01ADC. PDS01ADC is a novel investigational tumor-targeting fusion protein of Interleukin 12 that enhances the proliferation, potency, infiltration and longevity of T cells in the tumor microenvironment and is therefore designed to overcome the limitations of cytokine therapy which today have resulted in high toxicity and limited therapeutic potential. The proprietary combination of Versamune plus PDS01ADC is designed to overcome tumor immune suppression utilizing a different mechanism from immune checkpoint inhibitors (ICI). The ownership of both assets we believe will streamline the registrational process and its use. The combination of Versamune® and IL-12 to overcome immune suppression is patented by PDS Biotech. In a Phase 2 National Cancer Institute (NCI)-led clinical trial in ICI resistant patients, the combination of PDS0101 and PDS01ADC administered with an investigational bi-functional ICI resulted in a median overall survival of approximately 20 months, which compares favorably to the historical median survival of 3-4 months reported in ICI resistant HPV-positive cancers when treated with ICIs and best reported median survival to date with systemic therapy of 8.2 months in ICI resistant head and neck cancer.

In February 2023, we announced a successful completion of a Type B meeting with the FDA for the triple combination of PDS0101 and PDS01ADC with an FDA-approved immune checkpoint inhibitor for the treatment of recurrent/metastatic, ICI resistant head and neck cancer that is positive for the human papilloma virus (HPV) type 16. In recent interactions with the FDA, we confirmed the required contents of a clinical protocol for the potential registrational trial.

In June 2023, an abstract was presented at the 2023 American Society of Clinical Oncology: Abstract number 6012, Safety and Efficacy of Immune Checkpoint Inhibitor (ICI) Naïve Cohort from Study of PDS0101 and Pembrolizumab in HPV16-Positive Head and Neck Squamous Cell Carcinoma (HNSCC). The abstract was also selected as one of the featured posters reviewed by an expert panel in the Head and Neck Cancer discussion session.

In September 2023, data on our investigational universal flu vaccine, PDS0202, were presented at the 9th European Scientific Working Group on Influenza (ESWI) conference. These data demonstrated broad neutralization across multiple influenza strains and provided protection against infection after challenging animals not previously exposed to flu with lethal doses of the pandemic H1N1 flu virus.

In October 2023, data demonstrating PDS0101 in combination with standard-of-care (SOC) chemoradiotherapy was associated with a rapid decline in human papillomavirus circulating cell-free DNA (ctHPV-DNA), a potential predictive biomarker of treatment response. The data from the IMMUNOCERV Phase 2 clinical trial were featured in an oral presentation at the American Society for Radiation Oncology Annual Meeting.

In October 2023, updated interim data based on an August 2nd cut off from our VERSATILE-002 Phase 2 clinical trial evaluating the combination of PDS0101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) which is the FDA-approved standard of care for first-line treatment of recurrent/ metastatic head and neck cancer was presented. The data was presented at a Company-sponsored key opinion leader roundtable.

In October 2023, interim safety and immune response data was presented for the first-in-human Phase1/2 clinical trial evaluating PDS01ADC in combination with current SOC chemotherapy, docetaxel, to treat metastatic castration sensitive and castration resistant prostate cancer. The data was featured in an oral presentation at the 11th Annual Meeting of the International Cytokine & Interferon Society.

In October 2023, immune response data from a preliminary analysis of a subset if patients in our VERSATILE-002 Phase 2 clinical trial was presented at the European Society for Medical Oncology Congress 2023.

In November 2023, we announced updated interim survival data from our NCI-led Phase 2 triple combination study.

In November 2023, preclinical data from our NCI-led trial including PDS0101, PDS01ADC and an HDAC inhibitor in ICI-resistant HPV-16 positive cancer was presented during a poster presentation at the Society for Immunotherapy of Cancer 38th Annual Meeting.

Clinical Candidate Pipeline

VERSATILE-002: PDS0101 + KEYTRUDA®

In November 2020, our VERSATILE-002 Phase 2 clinical trial evaluating the combination of PDS0101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) which is the FDA-approved standard of care for first-line treatment of recurrent/ metastatic head and neck cancer commenced. Enrollment in stage 2 of 2 for the ICI naïve arm and the ICI resistant arms are complete. The clinical trial will evaluate the efficacy and safety of this therapeutic combination as a first and second line treatment in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV16) infection.

In this PDS Biotech-sponsored trial patients whose cancer has returned following initial treatment or spread will be treated with the combination of PDS0101 and KEYTRUDA® to evaluate if the addition of PDS0101 might improve the efficacy reported in published studies of KEYTRUDA ® alone. Patients in the trial will receive a total of 5 cycles of combination therapy in the context of standard of care KEYTRUDA® therapy administered every three weeks until disease progression. The primary endpoint of VERSATILE-002 is the objective response rate– or ORR – at six months following initiation of treatment. There are two cohorts in the trial. Cohort 1 is for patients who have yet to be treated with an immune checkpoint inhibitor (ICI naïve) and cohort 2 which consists of patients who have failed immune checkpoint inhibitor therapy (ICI resistant).

In February 2022, we achieved the preliminary efficacy milestone of at least four or more objective responses of the first 17 patients in the ICI naïve arm that allowed that arm to proceed to full enrollment. We also announced detailed preliminary safety data which showed that the combination is well tolerated without evidence of enhanced or significant toxicity in the first 18 patients in the ICI naïve arm. We have completed enrollment in Stage 1 of the ICI resistant arm and we are waiting for sufficient follow up to conduct the futility analysis.

In June 2022, we presented additional preliminary efficacy and safety data from this trial at the ASCO Annual Meeting (Weiss J et al. J Clin Oncol 40, 2022 (suppl 16; abstr 6041)). The abstract provided preliminary data on 19 patients (safety) with available imaging data for 17 of the 19 patients (efficacy). Data on 17 patients was presented. Highlights from the abstract were as follows:

- Confirmed and unconfirmed response rates thus far (tumor shrinkage greater than 30%) seen in 7/17 (41.2%) patients in comparison to the published results of approximately 19% for approved ICIs, used as monotherapy for recurrent or metastatic head and neck cancer, with 2 of the 7 having complete responses (CR)
- Stable disease (SD) was reported in 6/17 (35.3%) patients, with 4 of the 6 (67%) experiencing tumor shrinkage of less than 30%
- Clinical efficacy (ORR + SD) was seen in 13/17 (76.5%) patients
- Progressive/ongoing disease was reported in 4/17 (23.5%) patients

- Patients had received a median of 4/5 doses of PDS0101 (range 1-5) and 9/35 doses of KEYTRUDA® (range 1-18)
- There were no treatment-related adverse events greater than or equal to Grade 3 (N=19)
- No patients required dose interruption or reduction on the combination treatment
- No patients discontinued the combination treatment
- At 9 months of follow up (median not yet achieved):
  - Progression free survival (PFS) rate was 55.2%
  - Overall survival (OS) rate was 87.2%
- No control or comparative studies have been conducted between ICIs and PDS0101

In May 2022, we expanded this trial into Europe and in June 2022, as described above, we received Fast Track designation from the US FDA for PDS0101 in combination with pembrolizumab.

In August 2022, our independent Data Monitoring Committee (DMC) met and evaluated data from 43 patients and noted there were no Grade 3 or greater treatment-related adverse events attributed to the combination. The DMC recommended continuing the trial with no modifications.

In October 2022, we announced the results of an end-of-phase 2 meeting with the FDA for PDS0101 in combination with KEYTRUDA®. We have completed the plan for the Phase 3 clinical program that will support the submission of a BLA for PDS0101 and have submitted to the FDA.

In December 2022, we completed the first stage of enrollment in the ICI resistant arm. Cohort follow-up is in progress that will permit a futility analysis to determine progression to stage 2 enrollment is in progress.

In May 2023, we completed enrollment in the ICI naïve arm. We filed our amended IND with the FDA in the third quarter of 2023. In October 2023, we received feedback from the FDA on the amended IND. Later in October, as part of business development discussions, we received insights from a potential business partners on the Phase 3 clinical protocol. The clinical and medical teams are currently evaluating this feedback and therefore plan to initiate a Phase 3 trial, VERSATILE-003 in the first quarter of 2024.

In June 2023, an abstract was presented at the 2023 American Society of Clinical Oncology: Abstract number 6012, Safety and Efficacy of Immune Checkpoint Inhibitor (ICI) Naïve Cohort from Study of PDS0101 and Pembrolizumab in HPV16-Positive Head and Neck Squamous Cell Carcinoma (HNSCC). The abstract was also selected as one of the featured posters to be reviewed by an expert panel in the Head and Neck Cancer discussion session. Data on 34 patients was presented. The data from the abstract is as follows:

- Estimated 12-month overall survival rate was 87.1%. Published results are 36-50% with approved ICIs used alone.
- Median progression-free survival was 10.4 months (95% CI 4.2, 15.3). Published results are median PFS of 2-3 months for approved ICIs when used as monotherapy in patients with similar PD-L1 levels.
- A disease control rate (disease stabilization or tumor shrinkage) of 70.6% (24/34)
- Confirmed and unconfirmed objective response rate is 41.2% (14/34 patients), which is identical to the preliminary response rate data PDS Biotech previously reported at ASCO 2022 (7/17 patients). To date these responses have been confirmed in nine of the 34 patients (26.5%), including one complete response.
- 15/34 patients (44.1%) had stable disease.
- 9/34 patients (26.5%) had progressive disease.
- 4/48 (8.3%) of patients had a Grade 3 treatment-related adverse event (TRAE). No Grade 4 or higher TRAEs were observed.

In October 2023, at a key opinion roundtable updated interim data was presented based on an August 2nd cut off from our VERSATILE-002 Phase 2 clinical trial evaluating the combination of PDS0101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) which is the FDA-approved standard of care for first-line treatment of recurrent/ metastatic head and neck cancer. Data on 52 patients was presented. The data from the roundtable based on investigator assessment were as follows:

Highlights from the ICI naïve cohort include:

- 24-month overall survival (OS) rate is 74%; published 24-month survival rate of less than 30% for approved ICI.
- 12-month OS rate is 80%; published results of 30-50% with approved ICIs[1].
- Tumor shrinkage seen in 60% (31/52) of patients.
- Confirmed overall response rate (ORR) is 27% (14/52) to date.
- Median progression-free survival (PFS) is 8.1 months to date; published results of 2-3 months PFS with approved ICIs.
- 13% (8/62) of patients experienced Grade 3 treatment-related adverse events (TRAE) and 0% (0/62) experienced Grade 4 or 5 TRAE; published results report 13-17% Grade 3-5 TRAE with approved ICI monotherapy.
- 60% (33/55) of patients have CPS score of 1-19 (who generally have a weaker response to KEYTRUDA®), and 40% (22/55) have CPS score >20 (who generally have a higher response to KEYTRUDA®).

Highlights form the ICI refractory cohort include:

- The 12-month OS rate is 56%. The published median 12-month OS rate is 17% with no salvage chemotherapy following tumor progression on ICI (ICI Resistant).
- 0% (0/21) confirmed ORR suggests that PDS0101's impact on survival does not appear to be dependent on tumor shrinkage.
- 4% (1/25) of patients experienced Grade 3 TRAE and 0% (0/21) patients experienced Grade 4 and 5 TRAE.

National Cancer Institute: PDS0101+ M9241 (now PDS01ADC) +Bintrafusp Alfa

In June 2020, the first patient was dosed under a PDS0101 Cooperative Research and Development Agreement (CRADA), in the NCI led Phase 2 investigator-initiated trial evaluating PDS0101 with an IL-12 ADC now PDS01ADC, and M7824 (Bintrafusp alfa), which is owned by EMD Serono (Merck KGaA) in patients with advanced HPV-positive cancers who have failed prior treatment. In February 2021, the NCI's Phase 2 clinical trial of PDS0101 for the treatment of advanced HPV-positive cancers had achieved its preliminary objective response target in patients naïve to check point inhibitors which allowed for full enrollment of approximately 20 patients in this group. In addition, based on promising results in the ICI naïve arm, the trial was amended to allow enrollment of a separate cohort of IC -resistant patients for assessment of safety and activity of the triple combination. The trial has been closed for enrollment. Preliminary efficacy assessment of the triple combination in this added group of 29 ICI resistant patients has been completed and evaluation of long-term patient survival ongoing.

Preclinical study results arising from this CRADA were published in the Journal for ImmunoTherapy of Cancer, *Immunomodulation to enhance the efficacy of an HPV therapeutic vaccine (Journal for ImmunoTherapy of Cancer2020;8:e000612. Doi:10.1136/ jitc-2020-000612)*, and indicate that PDS0101 generated both HPV-specific T cells and an associated antitumor response when used as a monotherapy. When PDS0101 was combined with the two other novel clinical-stage anti-cancer agents, Bintrafusp Alfa and M9241 (which is now owned by us and referred to as PDS01ADC), the preclinical data suggested that all three therapeutic agents worked synergistically to provide superior tumor T cell responses and subsequent tumor regression when compared to any of the agents alone or the 2-component combinations. The published preclinical data demonstrating powerful activity of the triple combination appears to be corroborated in the Phase 2 trial, and this triple combination could form the basis of a unique platform providing improved cancer treatments across multiple cancers.

In June 2022, at the 2022 ASCO Annual Meeting, the NCI provided an update to the preliminary data presented at the 2021 meeting (Strauss J et al. *J Clin Oncol* 40, 2022 [suppl 16; abstr 2518]). This included data from 30 HPV16-positive patients and highlights were as follows:

- Objective response (OR = ≥30% tumor reduction) was seen in 88% (7/8) of patients with ICI naive disease; 4/7 (57%) patients' responses are ongoing (median 17 months).
- With ICI resistant patients: PDS0301 dosing appears to affect response rates, with 5/8 (63%) patients receiving PDS0301 at 16.8 mcg/kg achieving an OR compared to 1/14 (7%) patients who received PDS0301 at 8 mcg/kg achieving an OR; 4/6 (67%) patients' responses are ongoing (median 12 months).
- Tumor reduction was seen in 45% (10/22) of patients with ICI resistant disease, including patients receiving high or low dose PDS0301.
- In ICI resistant patients treated with high or low dose PDS0301, survival outcomes were similar (p=0.96 by Kaplan Meier analysis). At a median of 12 months of follow up 17/22 (77%) of patients were alive.
- In ICI naïve patients 6/8 (75%) were alive at median 17 months of follow up.
- Similar OR and survival were seen across all types of HPV16-positive cancers.
- Preliminary safety data: 13/30 (43%) of patients experienced Grade 3 treatment-related adverse events (AEs), and 2/30 patients (7%) experienced Grade 4 AEs. There were no grade 5 treatment-related AEs.

We believe the study results to date strongly suggest, in agreement with the published preclinical studies, that all 3 drugs contribute to the clinical outcomes.

In September 2022, we determined, in agreement with the NCI, to select the ICI resistant patients as the preferred treatment group in the on-going PDS0101-based triple combination therapy in advanced HPV-positive cancers and the trial was closed to further enrollment given the ICI resistant arm had been fully recruited.

In October 2022, we presented additional interim data as follows:

- Survival data: 66% (19/29) of HPV16-positive ICI resistant patients in the cohort were alive at a median follow up of 16 months.
- Safety profile: 48% (24/50) patients experienced Grade 3 treatment-related adverse events (AEs), and 4% (2/50) patients experienced Grade 4 AEs. There were no Grade 3 treatment-related AEs.
- HPV16-positive ICI naïve patients: 75% (6/8) were alive at a median follow up of 25 months and 38% (3/8) of responders had a complete response.

In December 2022, we presented interim data as follows:

- Median OS was 21 months in 29 checkpoint inhibitor resistant patients who received the triple combination. The reported historical median OS in patients with ICI resistant disease is 3-4 months seen with checkpoint inhibitors and best reported median survival to date with systemic therapy of 8.2 months in ICI resistant head and neck cancer.
- In ICI naïve subjects, 75% remain alive at a median follow-up of 27 months. As a result, median OS had not yet been reached. Historically median OS for similar patients with platinum experienced ICI naïve disease is 7-11 months.
- Objective response rate (ORR) in ICI resistant patients who received the optimal dose of the triple combination is 63% (5/8). In current approaches ORR is reported to be less than 10%.
- ORR in ICI naïve patients with the triple combination is 88%. In current approaches ORR is reported to be less than 25% with FDA-approved ICIs in HPV-positive cancers.
- Safety data had not changed since October's update. 48% (24/50) of patients experienced Grade 3 (moderate) treatment-related adverse events (AEs), and 4% (2/50) patients experienced Grade 4 (severe) AEs, compared with approximately 70% of patients receiving the combination of ICIs and chemotherapy reporting Grade 3 and higher treatment-related AEs.

In February 2023, we announced the successful completion of a Type B meeting with the FDA for the combination therapy of PDS0101, PDS01ADC, and an FDA-approved immune checkpoint inhibitor for the treatment of recurrent/metastatic HPV-positive ICI-resistant head and neck cancer. We confirmed the required contents of the trial design for a potential registrational trial of the combination.

In November 2023, we released updated interim survival data as follows:

- 75% of immune checkpoint inhibitor (ICI) naïve patients remain alive at 36 months; published median overall survival (OS) in similar patients is 7-11 months
- 12-month survival rate in (ICI) resistant patients is 72%
- Median OS in ICI resistant HPV-positive patients is approximately 20 months; published median OS is 3.4 months

MD Anderson Cancer Center (IMMUNOCERV): PDS0101+ Chemoradiotherapy

In October 2020, another PDS0101 Phase 2 IIT was initiated with The University of Texas MD Anderson Cancer Center and is actively recruiting patients. This clinical trial is investigating the safety and anti-tumor efficacy of PDS0101 in combination with standard-of-care chemo-radiotherapy, or CRT, and their correlation with critical immunological biomarkers in patients with locally advanced cervical cancer. We believe that Versamune has strong T cell induction with the potential to enhance efficacy of the current standard of care CRT treatment in this indication with the FDA at this meeting.

In November 2022, data from this trial was included in a poster presentation at the 2022 SITC Annual Meeting which included the following:

- 9 of the 17 patients had completed a Day 170 post-treatment Positron Emission Tomography, Computed Tomography (PET CT) scan to assess the status of the cancer. This included 78% (7/9) of treated patients with advanced cervical cancer (FIGO stage III or IV).
- 100% (9/9) of patients treated with the combination of PDS0101 and CRT had an objective response.
- 89% (8/9) of patients treated with the combination of PDS0101 and CRT demonstrated a complete response (CR) on Day 170 by PET CT. One patient who received 3 of the 5 scheduled doses of PDS0101 showed signs of residual disease. One patient who had a CR died from an event unrelated to either their underlying disease or treatment.
- 1-year disease-free survival and 1-year overall survival of 89% (8/9) in patients treated with the combination of PDS0101 and CRT.
- As previously reported, data confirm PDS0101 treatment activates HPV16-specific CD8 T cells. This increase was not seen in patients who did not receive PDS0101. The increase in HPV16-specific T cells generated by the treatment is positively correlated with tumor cell death, suggesting cytotoxic CD8 T cells are important mediators of antigen-specific immunity.
- The data affirm that PDS0101 activates Type 1 interferon pathway in humans, mimicking the mechanism previously demonstrated in preclinical studies in animal models.
- Toxicity of PDS0101 remains limited to low-grade local injection site reactions.

In October 2023, data demonstrating PDS0101 in combination with standard-of-care (SOC) chemoradiotherapy was associated with a rapid decline in human papillomavirus circulating cell-free DNA (ctHPV-DNA), a potential predictive biomarker of treatment response. The data from the IMMUNOCERV Phase 2 clinical trial were featured in an oral presentation at the American Society for Radiation Oncology Annual Meeting which included the following:

- Earlier and greater proportion of ctDNA clearance with PDS0101 plus chemoradiation (CRT) vs. SOC CRT alone (81.3% clearance after 3 weeks vs. 30.3% with SOC (p=0.0018), and 91.7% of clearance at 5 weeks vs. 53.1% with SOC (p=0.0179).
- Baseline ctDNA levels correlated with the International Federation of Gynecology and Obstetrics (FIGO) stage and lymph node involvement; 100% of patients treated with PDS0101 had cancer that had spread to the lymph nodes.

Mayo Clinic: PDS0101 Monotherapy and in combination with KEYTRUDA®

In February 2022, we initiated an Investigator-Initiated Trial (ITT), MC200710, for PDS0101 alone or in combination with the immune checkpoint inhibitor, KEYTRUDA®, in patients with HPV-positive oropharyngeal cancer (HPV(+)OPSCC) at high risk of recurrence. The trial is being led by Drs. David Routman, Katharine Price, Kathryn Van Abel, and Ashish Chintakuntlawar at Mayo Clinic, a nationally and internationally recognized center of excellence for the treatment of head and neck cancers. We believe that this trial not only broadens our addressable patient population of those affected by the increasing incidence of HPV(+)OPSCC, but also allows us to better understand the activity of PDS0101 alone or in combination with KEYTRUDA® in earlier stages of disease. This trial is currently open for enrollment.

In this trial, treatment will be administered before patients proceed to transoral robotic surgery (TORS) with curative intent. Treatment in this setting is referred to as neoadjuvant treatment. PDS0101 has been shown to induce killer T cells that target and kill HPV-positive cancers, either alone or in combination with ICIs in preclinical studies, and in combination in clinical studies of patients with advanced recurrent/metastatic HPV-positive cancers. This trial will explore whether PDS0101 with or without checkpoint inhibition may increase HPV-specific anti-tumor responses, potentially resulting in tumor shrinkage, pathologic regression, and decreases in circulating tumor DNA (ctDNA).

PDS0102

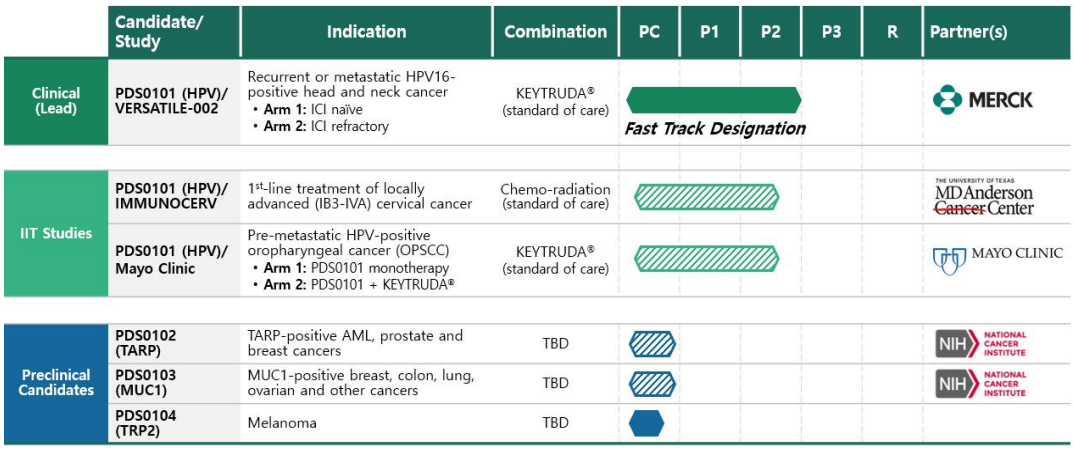
PDS0102 is an investigational immunotherapy utilizing tumor-associated and immunologically active T cell receptor gamma alternate reading framed protein (TARP) from the NCI. PDS0102 is designed to treat TARP-associated cancers including, acute myeloid leukemia (AML), prostate and breast cancer. In our preclinical work, in the administration of PDS0102, the Versamuine+TARP antigen combination led to the induction of large numbers of tumor targeted killer T cells. In addition, the TARP tumor antigen alone has already been studied at the NCI in men with prostate cancer and been shown to be safe, immunogenic with slowing tumor growth rates (NCT00972309). We are evaluating the next steps in the clinical development of PDS0102 and are seeking nondilutive financings to move the program into clinical trials.

PDS0103

In April 2020, the above mentioned PDS Biotech-NCI CRADA was expanded beyond PDS0101 to include clinical and preclinical development of PDS0103. PDS0103 is an investigational immune therapy owned by PDS Biotech and designed to treat cancers associated with the mucin-1, or MUC1, oncogenic protein. These include cancers such as ovarian, breast, colorectal and lung cancers. PDS0103 combines Versamune with novel highly immunogenic agonist epitopes of MUC1 developed by the NCI and licensed by PDS. PDS0103 is currently in the tech transfer and clinical scale up and manufacturing stage.

MUC1 is highly expressed in several types of cancer and has been shown to be associated with drug resistance and poor disease prognosis in breast, colorectal, lung and ovarian cancers, for which PDS0103 is being developed. Expression of MUC1 is often associated with poor disease prognosis, due in part to drug resistance. In preclinical studies, and similarly to PDS0101, PDS0103 demonstrated the ability to generate powerful MUC1-specific CD8 killer T cells. In the first quarter of 2022, we held a pre-IND meeting with the FDA on PDS0103 and we are prepared to submit our IND package by the first half of 2024. However, the actual submission date may potentially be impacted by the allocation of resources to initiate the pivotal trial for PDS0101. Our primary goal is commercialization of PDS0101, and allocation of resources to implement an earlier than planned start of a registrational trial may delay PDS0103 initiation.

Our current pipeline of Versamune based therapies is as follows:



IL-12 Oncology Immunocytokine Pipeline

PDS01ADC (formerly known as PDS0301/M9241 and NHS-IL-12) is a novel investigational IL12 fused antibody drug conjugate (IgG1), tumor-targeting interleukin 12 (IL-12) immune-cytokine that enhances the proliferation, potency and longevity of T cells in the tumor microenvironment. Together with Versamune based immunotherapies PDS01ADC works synergistically to overcome tumor immune suppression and to promote a targeted T cell attack against cancers. As with Versamune, PDS01ADC is given by a simple subcutaneous injection. Clinical data suggests the addition of PDS01ADC to Versamune based immunotherapies may demonstrate significant disease control in advanced cancer patients by shrinking tumors and/or prolonging life.

With the exclusive global license agreement with Merck KGaA, Darmstadt, Germany for PDS01ADC, we believe we have simplified our registrational pathway for the NCI-led triple combination by owning both PDS0101 and PDS01ADC and combining these agents with an FDA approved ICI. PDS01ADC has been designed to overcome the limitations of cytokine therapy as explained above, and based on extensive preclinical studies performed at the NCI evaluating PDS01ADC as a monotherapy and also in combinations with established standard of care treatments for cancer, we believe that PDS01ADC has significant potential as a cytokine therapy independent of Versamune. Based on the informative preclinical studies, a number of ITT Phase 2 trials are currently in progress at the NCI, some of which are outlined below:

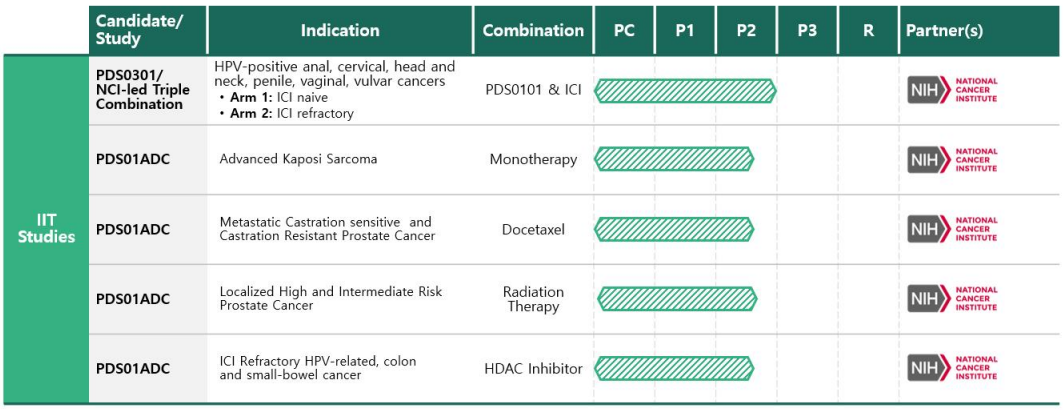
- Phase II Study Evaluating ICI Naïve and Resistant Patients with HPV-positive malignancies treated with PDS01ADC, PDS0101 and bintrafusp alfa.
- A Phase II Study Evaluating T-Cell Clonality After Stereotactic Body Radiation Therapy Alone and in Combination with the Immunocytokine PDS01ADCin Localized High and Intermediate Risk Prostate Cancer Treated with Androgen Deprivation Therapy
- A Phase I/II Study of PDS01ADC in Combination with Docetaxel in Adults with Metastatic Castration Sensitive and Castration Resistant Prostate Cancer
- Phase I/II of PDS01ADC going forward as a Monotherapy in Advanced Kaposi Sarcoma
- Phase I/II of PDS01ADC in Combination of with a Histone Deacetylase (HDAC) Inhibitor in ICI resistant MUC1-positive colon and bladder cancers among others

In October 2023, interim safety and immune response data was presented for the first-in-human Phase1/2 clinical trial evaluating PDS01ADC in combination with current SOC chemotherapy, docetaxel, to treat metastatic castration sensitive and castration resistant prostate cancer. The data was featured in an oral presentation at the 11th Annual Meeting of the International Cytokine & Interferon Society. Data presented as follows:

- Decrease in PSA levels was seen in all patients at all three tested doses of PDS0301 and 61% of patients had at least a 60% decrease in PSA levels.
- All doses of the combination were well-tolerated with one patient experiencing Grade 4 neutropenia.
- Administration of the combination was associated with decreases in T reg cells and increases in activated natural killer (NK) cells, memory CD8 T cells, proliferating CD4 and CD8 T cells and cytokines INF-γ and Interleukin 10 (IL-10).
- The changes in immune responses with the combination were independent of the PDS0301 dose.

We are working closely with the NCI to determine the best pathway forward for the prioritized PDS01ADC studies, as well as evaluating the use of PDS01ADC in combination with other Versamune based clinical candidates.

Our current pipeline of IL12 fused antibody conjugated PDS01ADC based therapies is as follows:



Infectimune Development Strategy

We believe that the key differentiating attributes of the Infectimune platform technology are strong induction of CD8 and CD4 T cells as well as antibodies which can be leveraged to improve treatment and preventive options in several infectious disease indications. In January 2022, we presented preclinical data on our universal flu program sponsored by the National Institute of Allergy and Infectious Disease (NIAID) demonstrating the potential of the Infectimune technology with computationally designed influenza proteins developed by the laboratory of Dr. Ted Ross at the University of Georgia to generate broadly protective anti-influenza immune responses across multiple strains of influenza. This data has provided a unique opportunity to highlight Infectimune's potentially transformative utility in the development of more broadly effective and longer lasting protective vaccines. 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.

Based on the promising data with the universal seasonal flu vaccine and the current focus of the NIAID in developing more effective flu vaccines, we have decided to opportunistically focus our near-term infectious disease activities to align with the interests of the NIAID Collaborative Influenza Vaccine Innovation Centers (CIVICs) program. This will involve development of a universal seasonal flu vaccine and the potential development of a universal pandemic influenza vaccine based on similar computationally designed antigens as have shown promise with Infectimune.

In July 2022, universal flu vaccine preclinical data for PDS0202 at the 41st American Society of Virology meeting: Abstract number 3733830, Infectimune enhances antibodies elicited by COBRA hemagglutinin influenza vaccine. We are evaluating the next steps in the clinical development and funding for PDS0202.

The results for Infectimune based vaccines were published in two separate articles in the peer reviewed journal *Viruses* in February 2023: 1. preclinical studies demonstrating complete protection against sickness after lethal challenge with live SARS-CoV-2 or influenza viruses (Gandhapudi SK et al. *Viruses* 2023, *15*, 432) and 2. Dramatically enhanced CD4 T cell responses to recombinant influenza proteins compared to leading commercial vaccine adjuvants (Henson TR et al. *Viruses* 2023, *15*, 538).

In September 2023, data on our investigational universal flu vaccine, PDS0202, were presented at the 9th European Scientific Working Group on Influenza (ESWI) conference. These data demonstrated active neutralization across multiple influenza viruses and provided protection against infection and weight loss after challenging with high doses of H1N1 viruses not previously exposed to flu.

Liquidity

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $32.0 million, and $21.7 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $133.6 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with these operations.

As of September 30, 2023, we had $54.3 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 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 license or acquire other products and technologies.

SELECTED FINANCIAL OPERATIONS OVERVIEW

Revenue

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

Research and Development Expenses

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

We expect that our research and development expenses will increase significantly over the next several years as we advance our platforms including Versamune based immuno-oncology, IL12 Fused antibody drug candidates in oncology, and Infectimune based infectious disease candidates into and through clinical trials, pursue regulatory approval of our investigational 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 clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval. The probability of successful commercialization of our drug candidates may be affected by numerous factors, including clinical data obtained in future trials, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Results of Operations

The following table summarizes the results of our operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Increase (Decrease)	
	2023	2022	$ Amount	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 6,449	$ 4,353	$ 2,096	48%
General and administrative expenses	4,071	2,926	1,145	39%
Total operating expenses	10,520	7,279	3,241	45%
Loss from operations	(10,520)	(7,279)	(3,241)	45%
Interest income (expense), net	(329)	(145)	(184)	127%
Net loss and comprehensive loss	$ (10,849)	$ (7,424)	$ (3,425)	46%

Research and Development Expenses

Research and development (R&D) expenses increased to $6.4 million for the three months ended September 30, 2023 from $4.4 million for the three months ended September 30, 2022. The increase of $2.0 million is primarily attributable to an increase of $1.3 million in clinical trials, and $0.7 million in personnel costs, including $0.3 million in non-cash stock-based compensation.

General and Administrative Expenses

General and administrative expenses increased to $4.1 million for the three months ended September 30, 2023 from $2.9 million for the three months ended September 30, 2022. The increase of $1.2 million is primarily attributable to an increase of $0.7 million in personnel costs, including $0.5 million in non-cash stock-based compensation, and $0.5 million in investor relations costs.

Comparison of the Nine months September 30, 2023 and 2022

The following table summarizes the results of our operations for the nine months September 30, 2023 and 2022:

	Nine Months Ended September 30,		Increase (Decrease)	
	2023	2022	$ Amount	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 20,297	$ 13,276	$ 7,021	53%
General and administrative expenses	12,341	9,575	2,766	29%
Total operating expenses	32,638	22,851	9,787	43%
Loss from operations	(32,638)	(22,851)	(9,787)	43%
Interest income (expense), net	(812)	(65)	(747)	1,149%
Benefit from income taxes	1,406	1,199	207	17%
Net loss and comprehensive loss	$ (32,044)	$ (21,717)	$ (10,327)	48%

Research and Development Expenses

Research and development (R&D) expenses increased to $20.3 million for the nine months September 30, 2023 from $13.3 million for the nine months ended September 30, 2022. The increase of $7.0 million was primarily attributable to an increase in personnel costs of $2.0 million, including $1.0 million in non-cash stock-based compensation, clinical trials of $3.4 million, manufacturing expenses of $1.4 million and professional fees and facilities costs of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased to $12.3 million for the nine months September 30, 2023 from $9.6 million for the nine months ended September 30, 2022. The increase of $2.7 million was primarily attributable to an increase in personnel costs of $2.0 million, including $1.4 million in non-cash stock-based compensation, and $0.7 million in investor relations costs.

Benefit from Income Taxes

Income tax benefit was $1.4 million for the nine months ended September 30, 2023 and $1.2 million for the nine months ended September 30, 2022. The increase of $0.2 million was due to an increase in the amount of New Jersey NOL carryforwards sold when compared to the comparable period.

Liquidity and Capital Resources

In April 2022, we received approximately $1.2 million from the net sale of tax benefits to an unrelated, profitable New Jersey corporation pursuant our participation in the New Jersey Technology Business Tax Certificate Transfer NOL program for tax year 2020.

In August 2022, we filed a shelf registration statement, or the 2022 Shelf Registration Statement, with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities, and units, up to an aggregate amount of $150 million, $50 million of which covers the offer, issuance and sale by us of our common stock under the Sales Agreement (as discussed below). The 2022 Shelf Registration Statement was declared effective on September 2, 2022.

In August 2022, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with B. Riley Securities, Inc. and BTIG, LLC, each an Agent and collectively the Agents, with respect to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $50 million, or the Placement Shares, through or to the Agents, as sales agents or principals. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Agents may sell the Placement Shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act of 1933, as amended, including, without limitation, sales made through The Nasdaq Capital Market or on any other existing trading market for our common stock. The Agents will use commercially reasonable efforts to sell the Placement Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay the Agents a commission equal to three percent (3%) of the gross sales proceeds of any Placement Shares sold through the Agents under the Sales Agreement, and also have provided the Agents with customary indemnification and contribution rights. We are not obligated to make any sales of our common stock under the Sales Agreement. The offering of Placement Shares pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Placement Shares subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. For the year ended December 31, 2022, we sold 1,238,491 shares of our common stock with a net value of $9.9 million pursuant to the Sales Agreement. During the three and nine months ended September 30, 2023, we sold 139,575 and 736,037 shares of our common stock with a net value of $0.8 million and $5.7 million, respectively, pursuant to the Sales Agreement.

In August 2022, we entered into a venture loan and security agreement, or the Loan and Security Agreement, with Horizon Technology Finance Corporation, as lender and collateral agent for itself and the other lenders. The Loan and Security Agreement provides for the following 6 separate and independent term loans: (a) a term loan in the amount of $7,500,000, or Loan A, (b) a term loan in the amount of $10,000,000, or Loan B, (c) a term loan in the amount of $3,750,000, or Loan C, (d) a term loan in the amount of $3,750,000, or Loan D, (e) a term loan in the amount of $5,000,000, or Loan E, and (f) a term loan in the amount of $5,000,000, or Loan F, (with each of Loan A, Loan B, Loan C, Loan D, Loan E, and Loan F, individually a Loan and, collectively, the Loans). Loan A, Loan B, Loan C, and Loan D were delivered to us on August 24, 2022. Loan E and Loan F were uncommitted Loans that could have been advanced by the Lenders upon the parties agreement prior to July 31, 2023 upon the satisfaction by the Company of certain agreed upon conditions. At this time the option has expired and Loan E and Loan F are no longer available to the Company under the Loan and Security Agreement . We may only use the proceeds of the Loans for working capital or general corporate purposes.

Each Loan matures on the 48-month anniversary following the applicable funding date unless accelerated pursuant to agreed upon events of default. Payments on the principal balance begin on October 1, 2024 and are paid monthly in the succeeding 24 months. The principal balance of each Loan bears a floating interest. The interest rate is calculated initially and, thereafter, each calendar month as the sum of (a) the per annum rate of interest from time to time published in The Wall Street Journal as contemplated by the Loan and Security Agreement, or any successor publication thereto, as the “prime rate” then in effect, plus (b) 5.75%; provided that, in the event such rate of interest is less than 4.00%, such rate shall be deemed to be 4.00% for purposes of calculating the interest rate.

Interest is payable on a monthly basis based on each Loan principal amount outstanding the preceding month. We, at our option upon at least ten (10) business days' written notice to the lenders, may prepay all (and not less than all) of the outstanding Loan by simultaneously paying to each lender an amount equal to (i) any accrued and unpaid interest on the outstanding principal balance of the Loans; plus (ii) an amount equal to (A) if such Loan is prepaid on or before the Loan Amortization Date (as defined in the Loan and Security Agreement) applicable to such Loan, 3% of the then outstanding principal balance of such Loan, (B) if such Loan is prepaid after the Loan Amortization Date applicable to such Loan, but on or before the date that is 12 months after such Loan Amortization Date, 2% of the then outstanding principal balance of such Loan, or (C) if such Loan is prepaid more than 12 months after the Loan Amortization Date but prior to the stated maturity date applicable to such Loan, 1% of the then outstanding principal balance of such Loan; *plus* (iii) the outstanding principal balance of such Loan; *plus* (iv) all other sums, if any, that shall have become due and payable thereunder. No prepayment premium will be applied to any outstanding balance of any Loan paid on the stated maturity date.

In connection with the Loan and Security Agreement, we issued Horizon Technology Finance Corporation and Powerscourt Investments XXV, LP warrants to purchase an aggregate total of 381,625 shares of our common stock at an initial exercise price of $3.6685 per share. Each warrant is classified as equity and is exercisable at any time for a period beginning on the date of grant and ending on the earlier of (A) 10 years from the date of grant, and (B) the closing of (A) (i) the sale, lease, exchange, conveyance or other disposition of all or substantially all of the our property or business, or (ii) its merger into or consolidation with any other corporation (other than a wholly-owned subsidiary of the Company), or any transaction (including a merger or other reorganization) or series of related transactions, in which more than 50% of the voting power of the Company is disposed of, in each case, for cash or for marketable securities meeting certain requirements as described in the applicable warrants. The key assumptions used in Black-Scholes option pricing model were (i) expected term of 10 years, (ii) a risk-free rate of 3.11%, (iii) expected volatility of 93.8%, and (iv) no estimated dividend yield.

In April 2023, we received approximately $1.4 million from the net sale of tax benefits to an unrelated, profitable New Jersey corporation pursuant our participation in the New Jersey Technology Business Tax Certificate Transfer NOL program for tax year 2021.

As of September 30, 2023, we had $54.3 million in cash and cash equivalents. Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financings. However, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our existing stockholders. We may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our clinical 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.

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 after the filing of this Quarterly Report on Form 10-Q. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings, there is no assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. As such, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these unaudited condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (25,179)	$ (18,181)
Net cash provided by financing activities	5,610	24,581
Net increase in cash and cash equivalents	$ (19,569)	$ 6,400

Net Cash Used in Operating Activities

Net cash used in operating activities was $25.2 million and $18.2 million for the nine months ended September 30, 2023 and 2022, respectively. The increase in net cash used in operating activities of $7.0 million was primarily due to an increase in net loss of $10.3 million, reduced by the increase in the non-cash stock-based compensation expense of $2.4 million, offset by changes in the timing of working capital requirements, including changes in prepaid expenses and other assets, accrued expenses and accounts payable. The increase in accounts payable, specifically, is primarily the result of a dispute with a certain vendor and we are working towards resolving this dispute.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was due to the receipt of net proceeds of $5.6 million due to the sale of common stock under the Sales Agreement. Net cash provided by financing activities for the nine months ended September 30, 2022 was primarily due to the receipt of net proceeds of $24.6 million due to the Venture Loan.

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 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 after the filing of this Quarterly Report. Our budgeted cash requirements in 2023 and beyond include expenses related to continuing development and clinical studies. 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. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings, there is no assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. As such, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these unaudited condensed consolidated financial statements.

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, 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 products on our own; and
- the initiation, progress, timing and results of our commercialization of our clinical candidates, if approved, for commercial sale.

Please see the section titled “Risk Factors” elsewhere in the Quarterly Report and Annual 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 Policies 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. Our accounting policies are more fully described in Note 2 to the consolidated financial statements included in this Quarterly Report on Form 10-Q. As described in Note 2, 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. Estimates are assessed each period and updated to reflect current information. Actual results may differ from these estimates under different assumptions or conditions. We believe that the discussion in our management’s discussion and analysis addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management’s most difficult, subjective and complex judgments.

There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2023 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

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.

Smaller Reporting Company

As of January 1, 2021, we were no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. However, we remain a “smaller reporting company,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. We will cease to be a smaller reporting company if we have a non-affiliate public float in excess of $250 million and annual revenues in excess of $100 million, or a non-affiliate public float in excess of $700 million, determined on an annual basis. As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. We will continue to take advantage of some or all of the available exemptions.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business and from changes in the interest rate on our debt borrowings. These market risks are principally limited to interest rate fluctuations. As of September 30, 2023, our cash equivalents consisted of bank deposits and money market accounts and our debt is a variable interest rate instrument. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio and debt agreement, we do not believe an immediate 100 basis point increase in interest rates would have a material effect on the fair market value of our portfolio, and, accordingly, we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts. We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the three months ended September 30, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15 (e)) under the Securities Exchange Act of 1934, or the Exchange Act, as of the end of the period covered by this report. Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the quarter ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information in Note 9 to the Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference. There are no matters which constitute material pending legal proceedings to which we are a party other than those incorporated into this item by reference from Note 9 to our Condensed Consolidated Financial Statements for the quarter ended September 30, 2023 contained in this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

With the exception of the risk factor noted below, there have been no material changes from our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2022. However, 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, our Annual Report on Form 10-K for the year ended December 31, 2022 filed on March 28, 2023, including our financial statements and related notes contained therein, 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. 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.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses and utilized cash in operations since inception. In addition, as of September 30, 2023, we had approximately $54.3 million in cash and cash equivalents, and during the nine months ended September 30, 2023, we used $18.2 million of cash in operations and expect to continue to incur significant cash outflows and incur future additional losses to execute our operating plan. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings, there is no assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalents as of September 30, 2023, we have concluded that substantial doubt exists about our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report. If we are unsuccessful in securing sufficient financing, we may need to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects, or cease operations.

Our unaudited condensed consolidated financial statements included in this Quarterly Report have been prepared on a going concern basis under which an entity is able to realize its assets and satisfy its liabilities in the ordinary course of business. The unaudited condensed consolidated financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should we be unable to continue as a going concern within one year after the date that the financial statements are issued.

Our future operations are dependent upon the successful entry into collaborations, strategic alliances, or license agreements with third parties and/or on the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that we will be successful in completing these collaborations or alliances, equity or debt financing or in achieving profitability. As such, there can be no assurance that we will be able to continue as a going concern.

Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

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

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the quarter ended September 30, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted , terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.1+	Third Amended and Restated PDS Biotechnology Corporation 2014 Equity Incentive Plan (incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 *	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2 *	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS*	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith (unless otherwise noted as being furnished herewith)
\+ Indicates management compensatory plan or arrangement.

SIGNATURES

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

PDS Biotechnology Corporation

November 14, 2023 **By: /s/ Frank Bedu-Addo**
Frank Bedu-Addo
President and Chief Executive Officer
(Principal Executive Officer)

November 14, 2023 **By: /s/ Matthew Hill**
Matthew Hill
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Frank Bedu-Addo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PDS Biotechnology Corporation for the period ended September 30, 2023;

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

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

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

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

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

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

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

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

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

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

Dated: November 14, 2023

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

Exhibit 31.2

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

I, Matthew Hill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PDS Biotechnology Corporation for the period ended September 30, 2023;

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

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

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

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

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

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

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

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

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

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

Dated: November 14, 2023

/s/ Matthew Hill
Matthew Hill
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the accompanying Quarterly Report of PDS Biotechnology Corporation (the "Company"), on Form 10-Q for the quarter ended September 30, 2023 (the "Report"), I, Frank Bedu-Addo, President and Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 that:

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

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

Dated: November 14, 2023

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

Exhibit 32.2

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

In connection with the accompanying Quarterly Report of PDS Biotechnology Corporation (the "Company"), on Form 10-Q for the quarter ended September 30, 2023 (the "Report"), I, Matthew Hill, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 that:

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

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

Dated: November 14, 2023

/s/ Matthew Hill
Matthew Hill
Chief Financial Officer
(Principal Financial and Accounting Officer)