

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **August 1, 2019**

PDS Biotechnology Corporation

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-37568
(Commission File Number)

26-4231384
(I.R.S. Employer Identification No.)

300 Connell Drive, Suite 4000
Berkeley Heights, NJ
(Address of Principal Executive Offices)

07922
(Zip Code)

Registrant's Telephone Number, Including Area Code **(800) 208-3343**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

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

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

Item 2.02. Results of Operations and Financial Condition.

On August 1, 2019, PDS Biotechnology Corporation (the “Company”) issued a press release announcing its financial results for the three and six months ended June 30, 2019 and an update on the Company’s operations. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information set forth in this Current Report on Form 8-K (including Exhibit 99.1) is deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d)Exhibits.

Exhibit Number	Description
<u>99.1</u>	Press release dated August 1, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 1, 2019

PDS Biotechnology Corporation

By: /s/ Andrew Saik

Name: Andrew Saik

Title: Chief Financial Officer

PDS Biotechnology Reports Second Quarter 2019 Financial Results And Provides Business Update

Berkeley Heights, NJ, August 1, 2019 - PDS Biotechnology Corporation (“PDS Biotechnology”) (Nasdaq: PDSB), a clinical-stage immuno-oncology company pioneering the development of novel multifunctional immunotherapeutic products, today announced its financial results for the second quarter ended June 30, 2019.

Q2 2019 and Recent Business Highlights

- Signed Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute to perform a Phase 2 clinical study of PDS0101 in combination with other immune-modulating agents in advanced HPV-related cancers;
- Announced peer-reviewed publication in the *Journal of Immunology* supporting the novel mechanism of action of PDS’ proprietary Versamune® platform in cancer immunotherapy;
- Granted U.S. and European patents for Versamune - GM-CSF combination to overcome tumor immune suppression; and
- Appointed industry veteran Stephen Glover as Chairman of the Board.

“We have been working diligently over the past quarter to further validate our novel Versamune platform, which may have the ability to overcome critical mechanisms associated with ineffective immune responses leading to a superior anti-tumor effect. Our CRADA with the National Cancer Institute for a Phase 2 clinical study for PDS0101 and the peer-reviewed publication in the *Journal of Immunology* describing Versamune’s novel mechanism of action are evidence of the considerable progress we continue to make. Furthermore, the newly granted patents in the U.S. and Europe provides us with further protections around the Versamune platform, including our lead candidate, PDS0101,” commented Dr. Frank Bedu-Addo, President and Chief Executive Officer of PDS Biotechnology. “Looking ahead, we anticipate initiating three clinical studies for PDS0101 in the fourth quarter of this year and will provide additional updates over the coming months. These studies include a planned phase 2 combination study to evaluate PDS0101 in combination with Keytruda® in the treatment of head and neck cancer, a phase 2 study to evaluate PDS0101 in advanced HPV associated cancers, and an anticipated registration trial to evaluate PDS0101 monotherapy in the treatment of high-grade cervical dysplasia”

Second Quarter 2019 Financial Review

For the second quarter of 2019, net loss was approximately \$(3.9) million, or \$(0.75) per basic and diluted share, compared to a net loss of approximately \$(0.6) million, or \$(0.17) per basic and diluted share for the second quarter of 2018.

Research and development expenses totaled approximately \$1.9 million for the second quarter of 2019, compared to approximately \$0.2 million for the same period in 2018, an increase of 1017%. The increase of \$1.7 million is primarily attributable to an increase in external expenses for clinical studies of \$1.4 million and an increase of \$0.3 million in personnel costs.

For the second quarter of 2019, general and administrative expenses were approximately \$2.4 million compared with approximately \$0.4 million for the second quarter of 2018, an increase of 499%. The increase of \$2.0 million is primarily attributable to increases of \$0.5 million in personnel costs, \$0.5 million in D&O insurance, \$0.2 million for facilities expense, \$0.2 million for professional fees, \$0.3 million in legal fees and \$0.3 million in other operating expenses.

Total operating expenses for the second quarter of 2019 were approximately \$4.3 million, compared to total operating expenses of approximately \$0.6 million for the same period in 2018, an increase of 653%.

As of June 30, 2019, the Company's cash balance was approximately \$21.7 million.

About PDS Biotechnology

PDS Biotechnology is a clinical stage immuno-oncology company with a growing pipeline of clinical-stage immunotherapies to treat various early-stage and late-stage cancers, including head and neck cancer, cervical, anal, prostate, breast and other cancers.

PDS Biotechnology's lead product candidate, PDS0101 (Versamune®-HPV) is a proprietary clinical stage immunotherapeutic administered by subcutaneous injection being developed to treat HPV-associated cancers such as head and neck cancers and anal cancers, both of which are widely reported to be increasing in frequency over the last decade, as well as cervical, penile, vaginal and vulvar cancers and their pre-cancerous conditions. In a human Phase 1/2a clinical study, PDS0101 monotherapy demonstrated potent *in-vivo* induction of the critical phenotype of tumor-attacking killer (CD8) T-cells, and induction of memory T-cells. No dose-limiting toxicities were observed in this study, suggesting potential for a rare combination of potency and safety among immunoncology therapeutics.

For additional information about PDS, please visit www.pdsbiotech.com.

Forward Looking Statements

This communication 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 PDS Biotechnology Corporation (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," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. 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 ability of the Company to integrate Edge and PDS Biotechnology following the merger; the Company's ability to protect its intellectual property rights; competitive responses to the completion of the merger; potential adverse reactions or changes to business relationships resulting from the completion of the merger; the Company's ability to access capital markets, the timing for the Company to initiate three planned clinical trials for its lead asset, PDS0101; the successful implementation of the Company's research and development programs and collaborations; the acceptance by the market of the Company's product candidates, if approved; and other factors, including legislative, regulatory, political and economic developments not within the Company's control. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's annual and periodic reports filed with the SEC. The forward-looking statements are made only as of the date of this press release and, except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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(Financial Statements to Follow)

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Balance Sheets

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,734,152	\$ 103,695
Prepaid expenses and other current assets	1,098,843	156,628
Total current assets	<u>22,832,995</u>	<u>260,323</u>
Property and equipment, net	368,987	29,508
Intangible assets, net	1,223,000	41,692
Right-to-use asset	<u>1,233,894</u>	-
Other assets	<u>145,470</u>	<u>12,800</u>
Total assets	<u>\$ 25,804,346</u>	<u>\$ 344,323</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	\$ 1,853,306	\$ 1,412,951
Accrued expenses	638,186	601,889
Restructuring reserve	1,283,875	-
Operating lease liability- short term	<u>492,086</u>	-
Total current liabilities	<u>4,267,453</u>	<u>2,014,840</u>
Noncurrent liability:		
Deferred tax liability	157,000	-
Operating lease liability- long term	774,278	-
Convertible promissory notes payable	-	30,000
STOCKHOLDERS' EQUITY		
Preferred stock, 5,000,000 shares authorized at June 30, 2019 and December 31, 2018, 0 outstanding	-	-
Common stock, \$0.00033 par value, 75,000,000 shares authorized at June 30, 2019 and December 31, 2018, 5,177,487 shares and 3,417,187 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	1,709	1,128
Additional paid-in capital	38,686,233	19,311,529
Accumulated deficit	<u>(18,082,327)</u>	<u>(21,013,174)</u>
Total stockholders' equity	<u>20,605,615</u>	<u>(1,700,517)</u>
Total liabilities and stockholders' equity	<u>\$ 25,804,346</u>	<u>\$ 344,323</u>

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development expenses	\$ 1,886,934	\$ 168,606	\$ 2,916,937	\$ 369,744
General and administrative expenses	2,383,972	398,425	6,289,848	934,226
Total operating expenses	4,270,906	567,031	9,206,785	1,303,970
Loss from operations	(4,270,906)	(567,031)	(9,206,785)	(1,303,970)
Other income (expense):				
Gain on bargain purchase	209,449	–	11,939,331	–
Interest income	175,605	4	198,907	10
Interest expense	–	(804)	(606)	(1,763)
Net income (loss) and comprehensive income (loss)	(3,885,852)	(567,831)	2,930,847	(1,305,723)
Net income (loss) per share, basic	(0.75)	(0.17)	0.66	(0.41)
Net income (loss) per share, diluted	\$ (0.75)	\$ (0.17)	\$ 0.52	\$ (0.41)
Weighted average common shares outstanding, basic	5,175,837	3,338,214	4,466,025	3,170,804
Weighted average common shares outstanding, diluted	5,175,837	3,328,214	5,677,359	3,170,804