

**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): **May 14, 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 May 14, 2019, PDS Biotechnology Corporation (the “Company”) issued a press release announcing its financial results for the three months ended March 31, 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

[99.1](#) Press release dated May 14, 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: May 14, 2019

PDS Biotechnology Corporation

By: /s/ Andrew Saik

Name: Andrew Saik

Title: Chief Financial Officer

PDS Biotechnology Reports First Quarter 2019 Financial Results and Provides Business Update

Berkeley Heights, NJ, May 14, 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 first quarter ended March 31, 2019.

Q1 2019 and Recent Business Highlights

- Successfully completed merger with Edge Therapeutics and listed on the Nasdaq Capital Market;
- Strengthened Board of Directors with the appointment of industry veteran Stephen Glover.

“The first quarter of 2019 was an exciting period for PDS, as we successfully completed our merger with Edge Therapeutics and became a public company. Simultaneously, we strengthened both our management team and Board of Directors with industry veterans who we believe will help guide our strategic direction moving forward,” commented Dr. Frank Bedu-Addo, President and Chief Executive Officer of PDS Biotechnology. “As we look ahead, we are preparing to initiate three clinical studies of PDS0101 in the fourth quarter of this year, which includes; 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.”

First Quarter 2019 Financial Review

For the first quarter of 2019, net income was approximately \$6.8 million, or \$1.82 per basic share and \$1.47 per diluted share, compared to a net loss of approximately \$(0.7) million, or \$(0.24) per basic and diluted share for the first quarter of 2018.

Research and development expenses totaled approximately \$1.0 million for the first quarter of 2019, compared to approximately \$0.2 million for the same period in 2018, an increase of 412%. These expenses include employee-related expenses, licensing fees to use certain technology in PDS’ 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 PDS’ behalf.

For the first quarter of 2019, general and administrative expenses were approximately \$3.9 million compared with approximately \$0.5 million for the first quarter of 2018, an increase of 629%. The increase is primarily attributable to an increase in non-cash stock compensation expense of \$2.3 million and bonuses of \$0.4 million. In addition, there was an increase in D&O insurance of \$0.1 million, professional consulting fees of \$0.1 million, as well as legal fees of \$0.4 million.

Total operating expenses for the first quarter of 2019 were approximately \$4.9 million, compared to total operating expenses of approximately \$0.7 million for the same period in 2018, an increase of 570%.

The Company recognized a gain on bargain purchase of approximately \$11.7 million in connection with the merger with Edge. The gain represents the difference between the book value of Edge assets compared to the cash value of stock granted to legacy Edge shareholders.

As of March 31, 2019, the Company’s cash balance was approximately \$26.6 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 immuno-oncology 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 two 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>March 31, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,592,845	\$ 103,695
Prepaid expenses and other current assets	1,313,931	156,628
Total current assets	<u>27,906,776</u>	<u>260,323</u>
Property and equipment, net	412,735	29,508
Intangible assets, net	1,223,000	41,692
Right-to-use assets	1,347,557	-
Other assets	<u>155,670</u>	<u>12,800</u>
Total assets	<u>\$ 31,045,738</u>	<u>\$ 344,323</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	\$ 2,665,266	\$ 1,412,951
Accrued expenses	446,962	601,889
Restructuring reserve	1,948,596	-
Operating lease liability- short term	477,300	-
Total current liabilities	<u>5,538,124</u>	<u>2,014,840</u>
Noncurrent liability:		
Deferred tax liability	157,000	-
Operating lease liability- long term	902,972	-
Convertible promissory notes payable	-	30,000
STOCKHOLDERS' EQUITY		
Preferred stock, 5,000,000 shares authorized at March 31, 2019 and December 31, 2018, 0 outstanding	-	-
Common stock, \$0.00033 par value, 75,000,000 shares authorized at March 31, 2019 and December 31, 2018, 5,172,938 shares and 3,417,187 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	1,707	1,128
Additional paid-in capital	38,642,411	19,311,529
Accumulated deficit	<u>(14,196,476)</u>	<u>(21,013,174)</u>
Total stockholders' equity	<u>24,447,642</u>	<u>(1,700,517)</u>
Total liabilities and stockholders' equity	<u>\$ 31,045,738</u>	<u>\$ 344,323</u>

PDS BIOTECHNOLOGY CORPORATION

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

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