# PDS Biotechnology Reports Third Quarter 2019 Financial Results and Provides Business Update

November 7, 2019

PRINCETON, N.J., Nov. 07, 2019 (GLOBE NEWSWIRE) -- PDS Biotechnology Corporation ("PDS Biotechnology") (Nasdaq: PDSB), a clinical-stage immuno-oncology company developing multiple therapies based on T-cell activating technology called Versamune® today announced its financial results for the third quarter ended September 30, 2019.

**Third Quarter 2019 and Recent Business Highlights**

- Reported promising Phase 1 clinical outcome data of PDS0101 in patients with cervical intraepithelial neoplasia (CIN) infected with multiple high-risk, cancer-causing types of human papillomavirus (HPV). The study demonstrated robust treatment-induced HPV16-specific killer T-cell (CD8+) responses as well as clearance of the disease and regression of lesions in 60% of evaluable patients;
- Announced clinical collaboration with Merck to evaluate PDS0101 in combination with KEYTRUDA® (pembrolizumab) in first line treatment of metastatic head and neck cancer;
- Completed manufacturing of clinical batches of PDS0101 for upcoming Phase 2 combination trials with Merck and National Cancer Institute; and
- Entered into a common stock purchase agreement with Aspire Capital Fund, LLC, to purchase up to an aggregate of $20.0 million of the Company's common stock.

"We are honored to partner with proven leaders in the field of immuno-oncology as we prepare to advance our lead candidate PDS0101 into multiple Phase 2 combination studies for various HPV-associated cancers," commented Dr. Frank Bedu-Addo, President and Chief Executive Officer of PDS Biotechnology. "We believe that our combination approach is supported by our recently announced Phase 1 clinical outcome data demonstrating not only lesion regression in 60% of evaluable patients, but also PDS0101's unique ability to promote the *in-vivo* induction of high levels of CD8+ T-cells. By promoting the induction of these tumor-specific CD8+ killer T-cells, our Versamune® platform could be critical to expanding clinical efficacy of checkpoint inhibitors and potentially address unmet patient needs for improved treatment options across a range of advanced cancers."

"In the first quarter of 2020, we anticipate initiating three studies including; a Phase 2combination study to evaluate PDS0101 in combination with KEYTRUDA® in the treatment of head and neck cancer, a Phase 2 study to evaluate PDS0101 in combination with two immunotherapies in advanced HPV associated cancers with the National Cancer Institute and a Phase 2a study to evaluate the combination of PDS0101 and chemoradiation in patients with locally advanced cervical cancer. We are working diligently to activate all three clinical programs and recently completed the manufacturing of clinical batches of PDS0101. The stock purchase agreement with Aspire also provides the Company with financial flexibility to support these trials," concluded Dr. Bedu-Addo.

**Third Quarter 2019 Financial Review**

For the third quarter of 2019, net loss was approximately $(5.8) million, or $(1.10) per basic and diluted share, compared to a net loss of approximately $(0.7) million, or $(0.21) per basic and diluted share for the third quarter of 2018.

Research and development expenses totaled approximately $1.8 million for the third quarter of 2019, compared to approximately $0.2 million for the same period in 2018, an increase of 845%. The increase of $1.6 million in 2019 was primarily attributable to an increase in external expenses for clinical studies of $1.1 million and an increase of $0.5 million in personnel costs.

For the third quarter of 2019, general and administrative expenses were approximately $3.1 million compared with approximately $0.5 million for the third quarter of 2018, an increase of 494%. The increase of $2.6 million is primarily attributable to increases in personnel costs of $0.5 million, D&O insurance of $0.5 million, stock-based consulting fees of $0.6 million, professional fees of $0.2 million, legal fees of $0.4 million and other operating expenses of $0.4 million.

Total operating expenses for the third quarter of 2019 were approximately $5.8 million, compared to total operating expenses of approximately $0.7 million for the same period in 2018, an increase of 723%.

As of September 30, 2019, the Company's cash balance was approximately $17.4 million.

**About PDS Biotechnology**

*About PDS Biotechnology*

PDS Biotechnology is a clinical-stage immune-oncology company developing multiple therapies based on T-cell activating technology. The company's proprietary Versamune® platform effectively delivers tumor-specific antigens for in-vivo uptake and processing, resulting in the production of antigen-specific T-cells. Using Versamune®, PDS Biotechnology is engineering therapies designed to better recognize cancer cells and break down their defense systems to effectively attack and destroy tumors. PDS Biotechnology's pipeline combines Versamune® technology with tumor-specific antigens across several cancer types. To learn more, please visit www.pdsbiotech.com.

*About PDS0101*

PDS Biotechnology's lead candidate, PDS0101, combines the utility of the Versamune® platform with a targeted antigen in HPV-expressing cancers. In partnership with Merck and the National Cancer Institute (NCI), PDS Biotechnology is advancing PD0101 to Phase 2 studies in head and neck cancer and in HPV-related advanced cancer.

**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 anticipated capital requirements, including the Company's anticipated cash runway and the Company's current expectations regarding its plans for future equity financings; the timing for the Company or its partners to initiate the planned clinical trials for its lead assets, PDS0101 and PDS0102; the Company's interpretation of the results of its Phase 1 trial for PDS0101 and whether such results are sufficient to support additional trials or the future success of such trials; 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; 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 product candidates; 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**

| | September 30, 2019 (unaudited) | December 31, 2018 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 17,406,608 | $ 103,695 |
| Prepaid expenses and other | 726,959 | 156,628 |
| Total current assets | 18,133,567 | 260,323 |
| | | |
| Property and equipment, net | 26,929 | 29,508 |
| Intangible assets, net | 1,223,000 | 41,692 |
| Other assets | – | 12,800 |
| | | |
| Total assets | $ 19,383,496 | $ 344,323 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| LIABILITIES | | |
| Current liabilities: | | |
| Accounts payable | $ 1,488,961 | $ 1,412,951 |
| Accrued expenses | 1,296,606 | 601,889 |
| Restructuring reserve | 858,332 | – |
| Total current liabilities | 3,643,899 | 2,014,840 |
| | | |
| Noncurrent liability: | | |
| Deferred tax liability | 157,000 | – |
| Convertible promissory notes payable | – | 30,000 |
| | | |
| STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Preferred stock, 5,000,000 shares authorized at September 30, 2019 and December 31, 2018, 0 outstanding | – | – |

| | | |
|---|---|---|
| Common stock, $0.00033 par value, 75,000,000 shares authorized at September 30, 2019 and December 31, 2018, 5,278,850 shares and 3,417,187 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively | 1,742 | 1,128 |
| Additional paid-in capital | 39,414,792 | 19,311,529 |
| Accumulated deficit | (23,833,937) | (21,013,174) |
| Total stockholders' equity (deficit) | 15,582,597 | (1,700,517) |
| Total liabilities and stockholders' equity (deficit) | $ 19,383,496 | $ 344,323 |

**PDS BIOTECHNOLOGY CORPORATION**

**Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)**

**(Unaudited)**

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

PDS Biotechnology

Source: PDS Biotechnology Corporation