

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 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): July 21, 2022

**PHARMACYTE BIOTECH, INC.**  
(Exact Name of Registrant as Specified in its Charter)

**Nevada**  
(State or other jurisdiction of incorporation)

**001-40699**  
(Commission File Number)

**62-1772151**  
(I.R.S. Employer Identification No.)

**3960 Howard Hughes Parkway, Suite 500**  
**Las Vegas, Nevada**  
(Address of Principal Executive Offices)

**89169**  
(Zip Code)

Registrant's telephone number, including area code: **(917) 595-2850**

N/A  
(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:

- 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))

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, Par Value \$0.0001 Per Share	PMCB	The Nasdaq Stock Market LLC

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

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.

**Item 8.01 Other Events.**

On July 21, 2022, PharmaCyte Biotech, Inc. (“PharmaCyte” or the “Company”) issued a press release providing an update with respect to the commencement of the pilot phase of its two-phase pig study. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

**Important Additional Information**

The Company, its directors and certain of its executive officers are participants in the solicitation of proxies from the Company’s shareholders in connection with the Company’s 2022 Annual Meeting of Stockholders. The Company intends to file a definitive proxy statement and a WHITE proxy card with the Securities and Exchange Commission (“SEC”) in connection with any such solicitation of proxies from the Company’s stockholders. STOCKHOLDERS OF THE COMPANY ARE STRONGLY ENCOURAGED TO READ SUCH PROXY STATEMENT, ACCOMPANYING WHITE PROXY CARD AND ALL OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION. The Company’s definitive proxy statement for the 2022 Annual Meeting of Stockholders will contain information regarding the direct and indirect interests, by security holdings or otherwise, of the Company’s directors and executive officers in the Company’s securities. Information regarding subsequent changes to their holdings of the Company’s securities can be found in the SEC filings on Forms 3, 4, and 5, which are available on the Company’s website at <https://ir.pharmacyte.com/all-sec-filings> or through the SEC’s website at [www.sec.gov](http://www.sec.gov). Information can also be found in the Company’s Annual Report on Form 10-K for the year ended April 30, 2022 to be filed with the SEC and in subsequent filings with the SEC. Updated information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in the definitive proxy statement and other materials to be filed with the SEC in connection with the 2022 Annual Meeting of Stockholders. Stockholders will be able to obtain the definitive proxy statement, any amendments or supplements to the proxy statement and other documents filed by the Company with the SEC at no charge at the SEC’s website at [www.sec.gov](http://www.sec.gov). Copies will also be available at no charge at the Company’s website at <https://ir.pharmacyte.com/all-sec-filings>.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Number</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated July 21, 2022, of PharmaCyte Biotech, Inc.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

## SIGNATURES

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

Date: July 21, 2022

**PHARMACYTE BIOTECH, INC.**

By: /s/ Kenneth L. Waggoner  
Kenneth L. Waggoner  
Chief Executive Officer,  
President and General Counsel



## PharmaCyte Biotech Commences First Phase of Two-Phase Pig Study

LAS VEGAS, NV, July 21, 2022--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (NASDAQ: PMCB), a biotechnology company focused on developing cellular therapies for cancer, diabetes, and malignant ascites using its signature live-cell encapsulation technology, Cell-in-a-Box®, announced today that it has commenced the pilot phase of its two-phase pig study. The pig study is the last of several requirements PharmaCyte has complied with related to the requests from the U.S. Food and Drug Administration (FDA) to lift the clinical hold on PharmaCyte's planned Phase 2b clinical trial for locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, explained, "As part of the Investigational New Drug Application process in preparation for our planned clinical trial in LAPC, the FDA requested data in a large animal, such as a pig, which allows for assessment of safety and distribution of CypCaps™ following infusion using the clinical route of application, devices, and procedures.

"The study will be conducted in two phases. The first phase, which began today, is a short pilot study in two pigs. The objective of this pilot study is to assess microcatheter-based delivery of CypCaps in the pancreatic arterial system. Volume of dose, number of CypCaps, and treatment location will be evaluated using imaging and histology. Also, the CypCaps used in the study will contain radiopaque microspheres, which will be evaluated to track the movement of the CypCaps.

"The data obtained from the pilot study will allow us to finalize the full-scale pig study protocol, which will involve 90 pigs. We will then present the protocol to the FDA in our planned Type A meeting which will provide us an opportunity to interact with the FDA to receive guidance on this and several other outstanding issues relating to the clinical hold. Subject to any FDA-suggested modifications to the protocol, we are fully prepared to carry on with the full-scale study. We feel that this strategy will provide the greatest likelihood for ultimate success."

The pilot study will involve two 90-pound Yorkshire pigs. They will receive a single intra-arterial injection of 100 CypCaps into the pancreatic arterial system through a microcatheter. Fluoroscopy will be used to qualitatively evaluate parameters such as vascular anatomy, treatment site suitability, and acute deployment characteristics. Over the course of a week, the animals will be clinically observed, given health and incision site checks, and body weight and condition will be scored.

At the conclusion of the clinical phase, whole blood and serum will be analyzed, and tissue will be collected including the pancreas and adjacent areas and CT imaged to evaluate potential spillover of the CypCaps containing radiopaque microspheres. After CT imaging is performed, various tissue sections will be histologically evaluated by a board-certified veterinary pathologist. Light microscopy will be used to examine collected tissues to evaluate for any adverse effects associated with implantation of the CypCaps. Evaluation of pancreatic samples will include the presence of microspheres, necrosis, fibroplasia, fibrosis, inflammation, mineralization/ossification, and evidence of vascular injury. Light microscopy of additional tissues will be reviewed to assess for adverse effects associated with treatment, including thrombosis, necrosis, inflammation, and presence of embolic material.

Both phases of the pig study are being conducted by CBSET, Inc., located in Lexington, Massachusetts.

To learn more about PharmaCyte's pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, we encourage you to watch PharmaCyte's documentary video complete with medical animations at: <https://www.PharmaCyte.com/Cancer>

### About PharmaCyte Biotech

PharmaCyte Biotech, Inc. is a biotechnology company developing cellular therapies for cancer, diabetes, and malignant ascites based upon a proprietary cellulose-based live-cell encapsulation technology known as "Cell-in-a-Box®." This technology is being used as a platform upon which therapies for several types of cancer, diabetes and malignant ascites are being developed.

PharmaCyte's therapy for cancer involves encapsulating genetically engineered human cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. For pancreatic cancer, these encapsulated cells are implanted in the blood supply to the patient's tumor as close as possible to the site of the tumor. Once implanted, a chemotherapy drug that is normally activated in the liver (ifosfamide) is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide flows through pores in the capsules, the live cells inside act as a "bio-artificial liver" and activate the chemotherapy drug at the site of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and we believe results in little to no treatment related side effects.

PharmaCyte's candidate therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes involves encapsulating a human cell line that has been genetically engineered to produce and release insulin in response to the levels of blood sugar in the human body. The encapsulation of the cell line will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, we anticipate that they will function as a "bio-artificial pancreas" for purposes of insulin production.

PharmaCyte's therapy for malignant ascites involves using the same encapsulated cells PharmaCyte employs for pancreatic cancer but placing the encapsulated cells in the peritoneal cavity of a patient and administering ifosfamide intravenously.

#### **Safe Harbor**

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that express the current beliefs and expectations of PharmaCyte's management and Board of Directors. Any statements contained in this press release which do not describe historical facts are forward-looking statements subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. Factors that could affect our actual results include our ability to satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IND removed, as well as such other factors that are included in the periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

More information about PharmaCyte Biotech can be found at <https://www.PharmaCyte.com>. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20220721005301/en/>

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Source: PharmaCyte Biotech, Inc.