

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended October 31, 2023

or

☐ 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 001-40699

PHARMACYTE BIOTECH, INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation or organization)

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

3960 Howard Hughes Parkway, Suite 500, Las Vegas, NV 89169
(Address of principal executive offices)

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

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 \$0.0001 Per Share	PMCB	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

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 (§232.405) 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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 ☒

As of December 13, 2023, the registrant had 8,615,640 outstanding shares of common stock, with a par value of \$0.0001 per share.

PHARMACYTE BIOTECH, INC.
INDEX TO QUARTERLY REPORT ON FORM 10-Q
THREE AND SIX MONTHS ENDED OCTOBER 31, 2023

	<u>Page</u>
PART I. FINANCIAL INFORMATION	3
Item 1. Condensed Consolidated Financial Statements (Unaudited)	3
Condensed Consolidated Balance Sheets as of October 31, 2023 and April 30, 2023 (Unaudited)	3
Condensed Consolidated Statements of Operations for the Three and Six Months Ended October 31, 2023 and 2022 (Unaudited)	4
Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three and Six Months Ended October 31, 2023 and 2022 (Unaudited)	5
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity for the Six Months Ended October 31, 2023 and 2022 (Unaudited)	6
Condensed Consolidated Statements of Cash Flows for the Six Months Ended October 31, 2023 and 2022 (Unaudited)	7
Notes to Condensed Consolidated Financial Statements (Unaudited)	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 3. Quantitative and Qualitative Disclosures About Market Risk	38
Item 4. Controls and Procedures	39
PART II. OTHER INFORMATION	40
Item 1. Legal Proceedings	40
Item 1A. Risk Factors	40
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	40
Item 3. Defaults Upon Senior Securities	41
Item 4. Mine Safety Disclosures	41
Item 5. Other Information	41
Item 6. Exhibits	41
Signatures	42

PART I – FINANCIAL INFORMATION

Item 1. Financial Information.

PHARMACYTE BIOTECH, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	October 31, 2023	April 30, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,425,269	\$ 68,039,936
Prepaid expenses and other current assets	323,189	107,681
Total current assets	73,748,458	68,147,617
Other assets:		
Intangibles	3,549,427	3,549,427
Investment in SG Austria	1,572,193	1,572,193
Other assets	7,688	7,688
Total other assets	5,129,308	5,129,308
Total Assets	\$ 78,877,766	\$ 73,276,925
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 126,163	\$ 128,281
Accrued expenses	1,018,155	458,300
Accrued Series B convertible preferred stock redemptions and dividends	4,095,271	–
Total current liabilities	5,239,589	586,581
Other liabilities:		
Warrant liability	11,504,000	–
Derivative liability	4,069,000	–
Total other liabilities	15,573,000	–
Total Liabilities	20,812,589	586,581
Commitments and Contingencies (Notes 6 and 8)		
Convertible Preferred Stock:		
Series B convertible preferred stock: authorized 35,000 shares, \$0.0001 par value and \$1,000 face value, 31,480 and 0 shares issued and outstanding excluding 3,520 and 0 shares subject to redemption as of October 31, 2023 and April 30, 2023, respectively. Liquidation preference of \$32,143,761 and 0, as of October 31, 2023 and April 30, 2023, respectively	21,297,669	–
Stockholders' equity:		
Preferred stock, authorized 10,000,000 shares	–	–
Series A preferred stock: authorized 1 share, \$0.0001 par value and 0 shares issued and outstanding as of October 31, 2023 and April 30, 2023	–	–
Common stock, authorized: 200,000,000 shares, \$0.0001 par value; 21,672,078 shares issued and 8,699,992 shares outstanding as of October 31, 2023 and 21,602,078 shares issued and 16,793,980 shares outstanding as of April 30, 2023	2,167	2,160
Additional paid-in capital	193,590,781	202,230,583
Accumulated deficit	(116,352,174)	(115,958,773)
Treasury stock, at cost, 12,972,086 and 4,808,098 shares as of October 31, 2023 and April 30, 2023, respectively	(40,449,123)	(13,560,623)
Accumulated other comprehensive loss	(24,143)	(23,003)
Total stockholders' equity	36,767,508	72,690,344
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity	\$ 78,877,766	\$ 73,276,925

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended October 31,		Six Months Ended October 31,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development costs	82,033	177,996	186,516	337,269
Compensation expense	229,159	400,420	469,157	728,138
Director fees	306,738	102,335	356,953	155,062
Legal and professional	519,073	1,454,826	844,301	2,351,047
General and administrative	272,517	183,043	1,627,919	427,712
Total operating expenses	<u>1,409,520</u>	<u>2,318,620</u>	<u>3,484,846</u>	<u>3,999,228</u>
Loss from operations	<u>(1,409,520)</u>	<u>(2,318,620)</u>	<u>(3,484,846)</u>	<u>(3,999,228)</u>
Other income (expenses):				
Interest income	894,181	439,171	1,770,059	578,673
Change in fair value of warrant liability	4,075,000	—	2,623,000	—
Change in fair value of derivative liability	(769,000)	—	(1,299,000)	—
Other expense	(765)	(1,058)	(2,614)	(4,964)
Total other income, net	<u>4,199,416</u>	<u>438,113</u>	<u>3,091,445</u>	<u>573,709</u>
Net income (loss)	<u>2,789,896</u>	<u>(1,880,507)</u>	<u>(393,401)</u>	<u>(3,425,519)</u>
Preferred stock dividends	(586,886)	—	(906,735)	—
Preferred stock accretion	<u>(4,461,097)</u>	<u>—</u>	<u>(7,733,130)</u>	<u>—</u>
Net loss attributable to common stockholders	<u>\$ (2,258,087)</u>	<u>\$ (1,880,507)</u>	<u>\$ (9,033,266)</u>	<u>\$ (3,425,519)</u>
Basic and diluted loss per share attributable to common stockholders	<u>\$ (0.26)</u>	<u>\$ (0.09)</u>	<u>\$ (0.85)</u>	<u>\$ (0.17)</u>
Weighted average shares outstanding basic and diluted	<u>8,765,134</u>	<u>20,585,451</u>	<u>10,683,514</u>	<u>20,742,383</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)

	Three Months Ended		Six Months Ended	
	October 31,		October 31,	
	2023	2022	2023	2022
Net income (loss)	\$ 2,789,896	\$ (1,880,507)	\$ (393,401)	\$ (3,425,519)
Other comprehensive income (loss):				
Foreign currency translation	(1,591)	(720)	(1,140)	584
Other comprehensive income (loss)	(1,591)	(720)	(1,140)	584
Comprehensive income (loss)	<u>\$ 2,788,305</u>	<u>\$ (1,881,227)</u>	<u>\$ (394,541)</u>	<u>\$ (3,424,935)</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
SIX MONTHS ENDED OCTOBER 31, 2023 AND 2022
(UNAUDITED)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount			
Balance, April 30, 2023	—	\$ —	21,602,078	\$ 2,160	\$ 202,230,583	(4,808,098)	\$ (13,560,623)	\$ (115,958,773)	\$ (23,003)	\$ 72,690,344
Stock issued for warrant exercise	—	—	70,000	7	63	—	—	—	—	70
Accrued preferred stock dividends	—	—	—	—	(319,849)	—	—	—	—	(319,849)
Preferred stock accretion	—	3,272,033	—	—	(3,272,033)	—	—	—	—	(3,272,033)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	451	451
Net loss	—	—	—	—	—	—	—	(3,183,297)	—	(3,183,297)
Repurchase of common stock	—	—	—	—	—	(8,085,879)	(26,721,897)	—	—	(26,721,897)
Issuance of Series B Preferred Stock, net of discounts and issuance costs of \$18,246,925	35,000	16,753,075	—	—	—	—	—	—	—	—
Balance, July 31, 2023	35,000	20,025,108	21,672,078	2,167	198,638,764	(12,893,977)	(40,282,520)	(119,142,070)	(22,552)	39,193,789
Series B preferred stock subject to redemption	(3,520)	(3,188,536)	—	—	—	—	—	—	—	—
Series B preferred stock dividends	—	—	—	—	(586,886)	—	—	—	—	(586,886)
Preferred stock accretion	—	4,461,097	—	—	(4,461,097)	—	—	—	—	(4,461,097)
Repurchase of common stock	—	—	—	—	—	(78,109)	(166,603)	—	—	(166,603)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(1,591)	(1,591)
Net income	—	—	—	—	—	—	—	2,789,896	—	2,789,896
Balance, October 31, 2023	31,480	\$ 21,297,669	21,672,078	\$ 2,167	\$ 193,590,781	(12,972,086)	\$ (40,449,123)	\$ (116,352,174)	\$ (24,143)	\$ 36,767,508
Balance, April 30, 2022	—	\$ —	20,721,047	\$ 2,072	\$ 201,582,107	—	\$ —	\$ (111,648,656)	\$ (15,757)	\$ 89,919,766
Stock issued for compensation	—	—	—	—	2,750	—	—	—	—	2,750
Stock issued for services	—	—	1,002	—	2,278	—	—	—	—	2,278
Stock-based compensation options	—	—	—	—	4,595	—	—	—	—	4,595
Stock issued for warrant exercise	—	—	880,000	88	792	—	—	—	—	880
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	1,304	1,304
Net loss	—	—	—	—	—	—	—	(1,545,012)	—	(1,545,012)
Repurchase of common stock	—	—	—	—	—	(851,981)	(2,090,847)	—	—	(2,090,847)
Balance, July 31, 2022	—	—	21,602,049	2,160	201,592,522	(851,981)	(2,090,847)	(113,193,668)	(14,453)	86,295,714
Stock issued for compensation	—	—	—	—	3,917	—	—	—	—	3,917
Stock options granted	—	—	—	—	4,212	—	—	—	—	4,212
Reverse stock split adjustment	—	—	29	—	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(720)	(720)
Net loss	—	—	—	—	—	—	—	(1,880,507)	—	(1,880,507)
Repurchase of common stock	—	—	—	—	—	(1,223,153)	(3,385,044)	—	—	(3,385,044)
Balance, October 31, 2022	—	\$ —	21,602,078	\$ 2,160	\$ 201,600,651	(2,075,134)	\$ (5,475,891)	\$ (115,074,175)	\$ (15,173)	\$ 81,037,572

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Six Months Ended October 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (393,401)	\$ (3,425,519)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	–	2,278
Stock issued for compensation	–	6,667
Stock-based compensation	–	8,807
Change in fair value of warrant liability	(2,623,000)	–
Change in fair value of derivative liability	1,299,000	–
Change in assets and liabilities:		
Decrease in prepaid expenses and other current assets	(215,508)	(162,637)
Increase (decrease) in accounts payable	(2,118)	655,916
Increase (decrease) in accrued expenses	293,632	(49,154)
Net cash used in operating activities	<u>(1,641,395)</u>	<u>(2,963,642)</u>
Cash flows from investing activities:		
Net cash provided by (used in) investing activities	<u>–</u>	<u>–</u>
Cash flows from financing activities:		
Repurchase of common stock	(26,622,277)	(5,475,891)
Proceeds from issuance of preferred stock, net of transaction costs	33,650,075	–
Proceeds from warrant exercise	70	880
Net cash provided by (used in) financing activities	<u>7,027,868</u>	<u>(5,475,011)</u>
Effect of currency rate exchange on cash and cash equivalents	<u>(1,140)</u>	<u>584</u>
Net increase (decrease) in cash and cash equivalents	5,385,333	(8,438,069)
Cash and cash equivalents at beginning of the periods	68,039,936	85,400,656
Cash and cash equivalents at end of the periods	<u>\$ 73,425,269</u>	<u>\$ 76,962,587</u>
Supplemental disclosure of cash flows information:		
Cash paid during the periods for income taxes	<u>\$ 1,600</u>	<u>\$ –</u>
Supplemental disclosure of cash flows information:		
Non-cash derivative liability at initial fair value	<u>\$ 2,770,000</u>	<u>\$ –</u>
Non-cash warrant liability at initial fair value	<u>\$ 14,127,000</u>	<u>\$ –</u>
Reclassification of Series B Convertible Preferred Stock and dividends to current liability	<u>\$ 4,095,271</u>	<u>\$ –</u>
Accretion of discounts to redemption value of Series B Preferred Stock	<u>\$ 7,733,130</u>	<u>\$ –</u>
Excise tax accrued on repurchase of common stock	<u>\$ 266,223</u>	<u>\$ –</u>

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1 – NATURE OF BUSINESS

PharmaCyte Biotech, Inc. (“Company”) is a biotechnology company focused on 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®.” The Cell-in-a-Box® technology is intended to be used as a platform upon which therapies for several types of cancer, including locally advanced, inoperable pancreatic cancer (“LAPC”) will be developed. The current generation of the Company’s product candidate is referred to as “CypCaps™.”

The Company is a Nevada corporation incorporated in 1996. In 2013, the Company restructured its operations to focus on biotechnology. The Company acquired licenses from SG Austria Pte. Ltd., a Singapore corporation (“SG Austria”) to treat cancer and Austrianova Singapore Pte. Ltd., a Singapore corporation (“Austrianova Singapore”) to treat diabetes using the Cell-in-the-Box technology. The restructuring resulted in the Company focusing all its efforts upon the development of a novel, effective and safe way to treat cancer and diabetes. In January 2015, the Company changed its name from Nuvilex, Inc. to PharmaCyte Biotech, Inc. to reflect the nature of its current business. In October 2021, the Company moved its headquarters from Laguna Hills, California to Las Vegas, Nevada.

On September 1, 2020, the Company submitted an Investigational New Drug Application (“IND”) to the United States Food and Drug Administration (“FDA”) for a planned clinical trial in LAPC. On October 1, 2020, the Company received notice from the FDA that it had placed the IND on clinical hold. On October 30, 2020, the FDA sent a letter to the Company setting forth the reasons for the clinical hold and specific guidance on what the Company must do to have the clinical hold lifted.

To lift the clinical hold, the FDA informed the Company that it needs to conduct several additional preclinical studies. The FDA also requested additional information regarding several topics, including DNA sequencing data, manufacturing information and product release specifications. The Company has been in the process of conducting these studies and gathering additional information to submit to the FDA. See “Investigational New Drug Application and Clinical Hold” below.

On August 15, 2022, the Company entered into a Cooperation Agreement (“Cooperation Agreement”) with Iroquois Master Fund Ltd. and its affiliates, pursuant to which the Company elected a reconstituted Board of Directors (“Board”). The Board has formed a Business Review Committee to evaluate, investigate and review the Company’s business, affairs, strategy, management and operations and in its sole discretion to make recommendations to the Company’s management and Board with respect thereto. The Business Review Committee is also reviewing many of the risks relative to the Company’s business. In addition, the Board is reviewing the Company’s development programs and its relationship with SG Austria, including that all licensed patents have expired, that know-how relating to the Company’s Cell-in-a-Box® technology solely resides with SG Austria, and that the incentives of SG Austria and its management may not be currently aligned with those of the Company. The Board has curtailed spending on the Company’s programs, including pre-clinical and clinical activities, until the review by the Business Review Committee and the Board is complete and the Board has determined the actions and plans to be implemented. The Business Review Committee’s recommendations will include potentially seeking a new framework for the Company’s relationship with SG Austria and its subsidiaries. In the event the Company is unsuccessful in seeking an acceptable new framework, the Company will reevaluate whether it should continue those programs which are dependent on SG Austria, including its development programs for LAPC, diabetes and malignant ascites. The issues involving SG Austria have delayed the Company’s timeline for addressing the FDA clinical hold for its planned clinical trial in LAPC and could result in other delays or termination of the development activities. In addition, the curtailment of spending on the Company’s programs pending the review by the Business Review Committee and the Board may cause additional delays.

The Cell-in-a-Box[®] encapsulation technology potentially enables genetically engineered live human cells to be used as a means to produce various biologically active molecules. The technology is intended to result in the formation of pinhead sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In a laboratory setting, this proprietary live cell encapsulation technology has been shown to create a micro-environment in which encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors and passage through catheters and needles, which the Company believes enables greater cell growth and production of the active molecules. The capsules are largely composed of cellulose (cotton) and are bioinert.

The Company has been developing therapies for pancreatic and other solid cancerous tumors by using genetically engineered live human cells that it believes are capable of converting a cancer prodrug into its cancer-killing form. The Company encapsulates those cells using the Cell-in-a-Box[®] technology and places those capsules in the body as close as possible to the tumor. In this way, the Company believes that when a cancer prodrug is administered to a patient with a particular type of cancer that may be affected by the prodrug, the killing of the patient's cancerous tumor may be optimized.

The Company has also been developing a way to delay the production and accumulation of malignant ascites that results from many types of abdominal cancerous tumors. The Company's therapy for malignant ascites involves using the same encapsulated cells it employs for pancreatic cancer but placing the encapsulated cells in the peritoneal cavity of a patient and administering ifosfamide intravenously.

In addition to the two cancer programs discussed above, the Company has been working on ways to exploit the benefits of the Cell-in-a-Box[®] technology to develop therapies for cancer that involve prodrugs based upon certain constituents of the *Cannabis* plant. However, until the FDA allows us to commence our clinical trial in LAPC and we are able to validate our Cell-in-a-Box[®] encapsulation technology in a clinical trial, we are not spending any further resources developing our Cannabis Program.

Finally, the Company has been developing a potential therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. The Company's product candidate for the treatment of diabetes consists of encapsulated genetically modified insulin-producing cells. The encapsulation will be done using the Cell-in-a-Box[®] technology. Implanting these encapsulated cells in the body is designed to have them function as a bio-artificial pancreas for purposes of insulin production.

Until the review by the Business Review Committee and the Board is complete and the Board has determined the actions and plans to be implemented, spending on the Company's programs has been curtailed.

Investigational New Drug Application and Clinical Hold

On September 1, 2020, the Company submitted an IND to the FDA for a planned clinical trial in LAPC. On October 1, 2020, the Company received notice from the FDA that it had placed the Company's IND on clinical hold. On October 30, 2020, the FDA sent the Company a letter setting forth the reasons for the clinical hold and providing specific guidance on what the Company must do to have the clinical hold lifted.

In order to address the clinical hold, the FDA requested that the Company:

- Provide additional sequencing data and genetic stability studies;
- Conduct a stability study on the Company's final formulated product candidate as well as the cells from the Company's Master Cell Bank;
- Evaluate the compatibility of the delivery devices (the prefilled syringe and the microcatheter used to implant the CypCaps[™]) with the Company's product candidate for pancreatic cancer;

- Provide additional detailed description of the manufacturing process of the Company's product candidate for pancreatic cancer;
- Provide additional product release specifications for the Company's encapsulated cells;
- Demonstrate comparability between the 1st and 2nd generation of the Company's product candidate for pancreatic cancer and ensure adequate and consistent product performance and safety between the two generations;
- Conduct a biocompatibility assessment using the Company's capsules material;
- Address specified insufficiencies in the Chemistry, Manufacturing and Controls information in the cross-referenced Drug Master File;
- Conduct an additional nonclinical study in a large animal (such as a pig) to assess the safety, activity, and distribution of the product candidate for pancreatic cancer; and
- Revise the Investigators Brochure to include any additional preclinical studies conducted in response to the clinical hold and remove any statements not supported by the data the Company generated.

The FDA also requested that the Company address the following issues as an amendment to the Company's IND:

- Provide a Certificate of Analysis for pc3/2B1 plasmid that includes tests for assessing purity, safety, and potency;
- Perform qualification studies for the drug substance filling step to ensure that the Company's product candidate for pancreatic cancer remains sterile and stable during the filling process;
- Submit an updated batch analysis for the Company's product candidate for the specific lot that will be used for manufacturing all future product candidates;
- Provide additional details for the methodology for the Resorufin (CYP2B1) potency and the PrestoBlue cell metabolic assays;
- Provide a few examples of common microcatheters that fit the specifications in the Company's Angiography Procedure Manual;
- Clarify the language in our Pharmacy Manual regarding proper use of the syringe fill with the Company's product candidate for pancreatic cancer; and
- Provide a discussion with data for trial of the potential for cellular and humoral immune reactivity against the heterologous rat CYP2B1 protein and potential for induction of autoimmune-mediated toxicities in our study population.

The Company assembled a scientific and regulatory team of experts to address the FDA requests. That team has been working diligently to complete the items requested by the FDA. The Company is conducting studies of the technology. The Company has completed the pilot study of two pigs and is evaluating the preliminary data before commencing the larger study of 90 pigs.

Nasdaq Listing

The Company's common stock began trading on Nasdaq on August 10, 2021, under the symbol "PMCB." Prior to that, the Company's common stock was quoted on the OTCQB Market under the symbol "PMCB."

Increase in Authorized Shares

On September 6, 2023, pursuant to stockholder approval received at a special meeting of stockholders, the Company filed with the Secretary of State of the State of Nevada a Certificate of Change to its Articles of Incorporation, as amended, to increase the number of authorized shares of common stock from 133,333,334 to 200,000,000. The Certificate of Change had no impact on the number of authorized shares of preferred stock, which remains at 10,000,000.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries. The Company operates independently and through four wholly owned subsidiaries: (i) PharmaCyte Biotech Europe Limited; (ii) PharmaCyte Biotech Australia Pty. Ltd.; and (iii) Viridis Biotech, Inc. and are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and the Rules and Regulations of the Commission. Upon consolidation, intercompany balances and transactions are eliminated. The Company's 14.3% investment in SG Austria is presented using the measurement alternative allowed under ASC 325 *Investments* for investments with no readily determinable fair value. In March 2023, Bio Blue Bird was liquidated and was de-consolidated in these consolidated financial statements.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in accordance with U.S. GAAP. U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities known to exist as of the date the financial statements are published and the reported amounts of revenues and expenses during the reporting period. Uncertainties with respect to such estimates and assumptions are inherent in the preparation of the Company's condensed consolidated financial statements; accordingly, it is possible that the actual results could differ from these estimates and assumptions, which could have a material effect on the reported amounts of the Company's condensed consolidated financial position and results of operations.

Cash and Cash Equivalents

Cash and cash equivalents include cash in banks and short-term liquid investments purchased with maturities of three months or less.

Intangible Assets

The Financial Accounting Standards Board (“FASB”) standard on goodwill and other intangible assets prescribes a two-step process for impairment testing of goodwill and indefinite-lived intangibles, which is performed annually, as well as when an event triggering impairment may have occurred. The first step tests for impairment, while the second step, if necessary, measures the impairment. The Company has elected to perform its annual analysis at the end of its reporting year.

The Company’s intangible assets are in process R&D obtained through the acquisition of licensing agreements related to the Cell-in-a-Box[®] technology for \$1,549,427 and diabetes license for \$2,000,000 for an aggregate total of \$3,549,427.

These intangible assets have an indefinite life; therefore, they are not amortizable.

The Company concluded that there was no impairment of the carrying value of the intangible assets for the six months ended October 31, 2023 and 2022.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be fully recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. No impairment indicators were identified or recorded during the six months ended October 31, 2023 and 2022.

Fair Value of Financial Instruments

The carrying amounts reflected in the Condensed Consolidated Balance Sheets for payables approximate fair value due to the short maturities of these instruments. The carrying amounts for warrant liability and derivative liability represent fair value based on level 3 of the fair value hierarchy.

Accounting Standards Codification (“ASC”) Topic 820, “Fair Value Measurements and Disclosures,” requires disclosure of the fair value of financial instruments held by the Company. ASC Topic 825, “Financial Instruments,” defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the Condensed Consolidated Balance Sheets for current assets and liabilities qualify as financial instruments and are a reasonable estimate of their fair values because of the short period between the origination of such instruments and their expected realization and their current market rate of interest. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of valuation hierarchy are defined as follows:

- Level 1. Observable inputs such as quoted prices in active markets;
- Level 2. Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions. These unobservable inputs are significant to the fair value measurement.

Income Taxes

Deferred taxes are calculated using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

A valuation allowance is provided for deferred income tax assets when, in management's judgment, based upon currently available information and other factors, it is more likely than not that all or a portion of such deferred income tax assets will not be realized. The determination of the need for a valuation allowance is based on an on-going evaluation of current information including, among other things, historical operating results, estimates of future earnings in different taxing jurisdictions and the expected timing of the reversals of temporary differences. The Company believes the determination to record a valuation allowance to reduce a deferred income tax asset is a significant accounting estimate because it is based on, among other things, an estimate of future taxable income in the U.S. and certain other jurisdictions, which is susceptible to change and may or may not occur, and because the impact of adjusting a valuation allowance may be material. In determining when to release the valuation allowance established against the Company's net deferred income tax assets, the Company considers all available evidence, both positive and negative. Consistent with the Company's policy, and because of the Company's history of operating losses, the Company does not currently recognize the benefit of all its deferred tax assets, including tax loss carry forwards, which may be used to offset future taxable income. The Company continually assesses its ability to generate sufficient taxable income during future periods in which deferred tax assets may be realized. When the Company believes it is more likely than not that it will recover its deferred tax assets, the Company will reverse the valuation allowance as an income tax benefit in the condensed consolidated statements of operations.

The U.S. GAAP method of accounting for uncertain tax positions utilizes a two-step approach to evaluate tax positions. Step one, recognition, requires evaluation of the tax position to determine if based solely on technical merits it is more likely than not to be sustained upon examination. Step two, measurement, is addressed only if a position is more likely than not to be sustained. In step two, the tax benefit is measured as the largest amount of benefit, determined on a cumulative probability basis, which is more likely than not to be realized upon ultimate settlement with tax authorities. If a position does not meet the more likely than not threshold for recognition in step one, no benefit is recorded until the first subsequent period in which the more likely than not standard is met, the issue is resolved with the taxing authorities or the statute of limitations expires. Positions previously recognized are derecognized when the Company subsequently determines the position no longer is more likely than not to be sustained. Evaluation of tax positions, their technical merits and measurements using cumulative probability are highly subjective management estimates. Actual results could differ materially from these estimates.

Consideration of Inflation Reduction Act Excise Tax

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IR Act") was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly-traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its stockholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of the Treasury (the "Treasury") has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

Any redemption or other repurchase that occurs after December 31, 2022 in connection with a Business Combination, extension vote or otherwise, may be subject to the excise tax. Whether and to what extent the Company would be subject to the excise tax in connection with a Business Combination, extension vote or otherwise would depend on a number of factors, including (i) the fair market value of the redemptions and repurchases in connection with the Business Combination, extension or otherwise, (ii) the structure of a Business Combination, (iii) the nature and amount of any “PIPE” or other equity issuances in connection with a Business Combination (or otherwise issued not in connection with a Business Combination but issued within the same taxable year of a Business Combination) and (iv) the content of regulations and other guidance from the Treasury. In addition, because the excise tax would be payable by the Company and not by the redeeming holder, the mechanics of any required payment of the excise tax have not been determined. The foregoing could cause a reduction in the cash available on hand to complete a Business Combination and impact the Company’s ability to complete a Business Combination.

The Company repurchased 8,163,988 shares of common stock with a total cost of \$26,622,277 during the six months ended October 31, 2023 and 78,109 shares of common stock with a total cost of \$164,953 for the three months ended October 31, 2023. The Company recorded \$266,223 in excise tax related to the IR Act, which is included in Treasury stock and a related accrual for the three and six months ended October 31, 2023.

Research and Development

Research and development (“R&D”) expenses consist of costs incurred for direct and overhead-related research expenses and are expensed as incurred. Costs to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in the Company’s product candidates is expensed as incurred until technological feasibility has been established.

R&D costs for the three months ended October 31, 2023 and 2022 were \$82,033 and \$177,996, respectively, and for the six months ended October 31, 2023 and 2022 were \$186,516 and \$337,269, respectively.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for only those awards ultimately expected to vest on a straight-line basis over the requisite service period of the award. The Company estimates the fair value of stock options using a Black-Scholes-Merton valuation model. This model requires the input of highly subjective assumptions, including the option’s expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management’s best estimates, but these estimates involve inherent uncertainties and the application of management’s judgment. Thus, if factors change and the Company uses different assumptions, the stock-based compensation expense could be materially different in the future.

Concentration of Credit Risk

The Company has no significant off-balance-sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains most of its cash balance at financial institutions located throughout the United States. Accounts at these institutions are insured by the Federal Deposit Insurance Corporation up to \$250,000. Uninsured balances aggregated approximately \$24,264,000 and \$1,060,000 at October 31, 2023 and 2022, respectively. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash and cash equivalents.

Foreign Currency Translation

The Company translates the financial statements of its foreign subsidiaries from the local (functional) currencies to U.S. dollars in accordance with FASB ASC 830, *Foreign Currency Matters*. All assets and liabilities of the Company’s foreign subsidiaries are translated at year-end exchange rates, while revenue and expenses are translated at average exchange rates prevailing during the year. Adjustments for foreign currency translation fluctuations are excluded from net loss and are included in other comprehensive income (loss). Gains and losses on short-term intercompany foreign currency transactions are recognized as incurred.

NOTE 3 – ACCRUED EXPENSES

Accrued expenses at October 31, 2023 and April 30, 2023, are summarized below:

	October 31, 2023	April 30, 2023
Payroll related costs	\$ 149,788	\$ 112,894
R&D costs, including related parties	287,310	287,310
Director compensation	256,738	–
Other, including excise tax on stock repurchases	324,319	58,096
Total	<u>\$ 1,018,155</u>	<u>\$ 458,300</u>

NOTE 4 – COMMON STOCK TRANSACTIONS

A summary of the Company's compensatory stock activity and related weighted average grant date fair value information for the three and six months ended October 31, 2023 and 2022 is as follows:

In January 2022, the Company awarded 4,400 shares of common stock to the executive officers of the Company as part of their compensation agreements for 2022. During the six months ended October 31, 2023 and 2022, the Company recorded a non-cash compensation expense in the amount of \$0 and \$3,917, respectively. There were zero and 6,667 unvested shares as of October 31, 2023 and 2022, respectively. Two of the executive officers terminated their services in October 2022 and pursuant to their separation agreements the shares were fully vested.

During the six months ended October 31, 2022, three non-employee members of the Board were issued 1,002 shares of common stock pursuant to their Director Letter Agreements ("DLAs") in respect of their service during that year. The shares were fully vested upon issuance. The Company recorded a non-cash expense of \$0 and \$0 for the three months ended October 31, 2023 and 2022, respectively, and \$0 and \$2,278 for the six months ended October 31, 2023 and 2022, respectively. There were zero unvested shares remaining related to such DLAs as of October 31, 2023 and 2022, respectively.

All shares were issued without registration under the Securities Act of 1933 as amended ("Securities Act") in reliance upon the exemption afforded by Section 4(a)(2) of the Securities Act.

There were no shares granted, vested or expired during the six months ended October 31, 2023.

NOTE 5 – STOCK OPTIONS AND WARRANTS

2022 Equity Incentive Plan

Effective December 28, 2022, the Company implemented the 2022 Equity Incentive Plan ("2022 Equity Plan") as approved by the Company's stockholders. The 2022 Equity Plan is administered by the Compensation Committee of the Board and has 2,750,000 shares available under this plan. The 2022 Equity Plan can issue various types of awards, as follows: stock options, stock appreciation rights, restricted stock, restricted stock units, and cash or other stock-based awards. The 2022 Equity Plan is available to be issued to employees, directors, consultants, and other individuals who provide services to the Company. An incentive stock options ("ISOs") can only be granted to employees and shall not exceed 10-years (5-years in the case of ISOs granted to any 10% shareholder).

Stock Options

As of October 31, 2023, the Company had 279,802 outstanding stock options to its directors and officers (collectively, “Employee Options”) and consultants (“Non-Employee Options”).

During the six months ended October 31, 2023 and 2022, the Company granted 0 and 1,002 Employee Options, respectively.

The fair value of the Employee Options at the date of grant was estimated using the Black-Scholes-Merton option-pricing model, based on the following weighted average assumptions:

	Six Months Ended October 31,	
	2023	2022
Risk-free interest rate	—	2.9%
Expected volatility	—	139%
Expected lives (years)	—	2.5
Expected dividend yield	—	0.00%

The Company’s computation of expected volatility is based on the historical daily volatility of its publicly traded stock. For stock option grants issued during the six months ended October 31, 2023 and 2022, the Company used a calculated volatility for each grant based on the Company’s historical stock values. The Company lacks adequate information about the exercise behavior now and has determined the expected term assumption under the simplified method provided for under ASC 718, which averages the contractual term of the Company’s stock options of five years with the average vesting term of two and one-half years for an average of three years. The dividend yield assumption of zero is based upon the fact the Company has never paid cash dividends and presently has no intention of paying cash dividends. The risk-free interest rate used for each grant is equal to the U.S. Treasury rates in effect at the time of the grant for instruments with a similar expected life.

A summary of the Company’s stock option activity and related information for the six months ended October 31, 2023, are shown below:

Options	Number of Options	Weighted Average Grant Date Fair Value per Share
Outstanding, April 30, 2023	281,269	\$ 6.94
Issued	—	—
Expired	(1,467)	89.10
Outstanding, October 31, 2023	279,802	\$ 6.50
Exercisable, October 31, 2023	279,802	\$ 6.50
Vested and expected to vest	279,802	\$ 6.50

There were no unvested stock options during the six months ended October 31, 2023.

The Company recorded \$0 and \$4,213 of stock-based compensation related to the issuance of Employee Options to certain officers and directors in exchange for services during the three months ended October 31, 2023 and 2022, respectively, and \$0 and \$8,808 during the six months ended October 31, 2023 and 2022, respectively. At October 31, 2023, there remained zero of unrecognized compensation expense related to unvested Employee Options granted to officers and directors.

The following table summarizes the outstanding stock options by exercise price at October 31, 2023:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (Years) of Outstanding Options	Weighted Average Exercisable Price Per Share	Number of Options Exercisable	Weighted Average Exercise Price Per Share of Exercisable Options
\$ 74.25	6,000	0.23	\$ 74.25	6,000	\$ 74.25
\$ 57.00	800	0.90	\$ 57.00	800	\$ 57.00
\$ 60.60	667	0.25	\$ 60.60	667	\$ 60.60
\$ 55.50	333	0.33	\$ 55.50	333	\$ 55.50
\$ 51.00	333	0.47	\$ 51.00	333	\$ 51.00
\$ 61.20	6,000	0.70	\$ 61.20	6,000	\$ 61.20
\$ 36.00	667	0.75	\$ 36.00	667	\$ 36.00
\$ 37.05	333	0.83	\$ 37.05	333	\$ 37.05
\$ 15.75	333	0.97	\$ 15.75	333	\$ 15.75
\$ 10.05	6,000	1.30	\$ 10.05	6,000	\$ 10.05
\$ 26.55	667	1.25	\$ 26.55	667	\$ 26.55
\$ 16.20	333	1.33	\$ 16.20	333	\$ 16.20
\$ 3.19	334	1.47	\$ 3.19	334	\$ 3.19
\$ 2.50	6,000	1.90	\$ 2.50	6,000	\$ 2.50
\$ 2.29	668	1.75	\$ 2.29	668	\$ 2.29
\$ 2.24	334	1.83	\$ 2.24	334	\$ 2.24
\$ 2.97	250,000	9.04	\$ 2.97	250,000	\$ 2.97
Total	<u>279,802</u>	8.19	\$ 6.50	<u>279,802</u>	\$ 6.50

The aggregate intrinsic value of outstanding options as of October 31, 2023 was \$0. This represents options with exercise prices less than the \$2.12 per share closing price of the Company's common stock on October 31, 2023.

Warrants

Pursuant to the Private Placement (as defined below), the Company issued investors Warrants (as defined below) to purchase 8,750,000 shares of Common Stock, with an exercise price of \$4.00 per share (subject to adjustment), for a period of five years from the date of issuance. For more information on the Private Placement, see "Note 11 – Preferred Stock".

The Warrants were determined to be within the scope of ASC 480-10 as they are puttable to the Company at Holders' election upon the occurrence of a Fundamental Transaction (as defined in the agreements). As such, the Company recorded the Warrants as a liability at fair value with subsequent changes in fair value recognized in earnings. The Company utilized the Black-Scholes-Merton Model to calculate the value of the Warrants issued during the six months ended October 31, 2023. The fair value of the Warrants of approximately \$14,127,000 was estimated at the date of issuance using the fair value of our common stock of \$2.74 on the issuance date and was based on the following weighted average assumptions: dividend yield 0%; expected term of 5.0 years; equity volatility of 80.0%; and a risk-free interest rate of 3.37%.

Transaction costs incurred attributable to the issuance of the Warrants of approximately \$0.9 million were immediately expensed in accordance with ASC 480 and is included in general and administrative expense in the accompanying Condensed Consolidated Statements of Operations.

During the six months ended October 31, 2023, the Company recorded a gain of approximately \$2,623,000 related to the change in fair value of the warrant liability which is recorded in other income (expense) on the Condensed Consolidated Statements of Operations. The fair value of the Warrants of \$11,504,000 was estimated at October 31, 2023, utilizing the Black-Scholes-Merton Model using the fair value of our common stock of \$2.12 and the following weighted average assumptions: dividend yield 0%; remaining term of 4.53 years; equity volatility of 95.0%; and a risk-free interest rate of 4.84%.

A summary of the Company's warrant activity and related information for the six months ended October 31, 2023, are shown below:

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, April 30, 2023	9,890,847	\$ 4.99
Issued	8,750,000	4.00
Exercised	(70,000)	—
Expired	—	—
Outstanding, October 31, 2023	18,570,847	—
Exercisable, October 31, 2023	18,570,847	\$ 4.54

The following table summarizes additional information concerning warrants outstanding and exercisable at October 31, 2023:

Exercise Prices	Number of Warrant Shares Exercisable at October 31, 2023	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price Per Share
\$ 4.25	1,506,141	2.78	
\$ 5.3125	264,706	2.78	
\$ 5.00	7,000,000	2.82	
\$ 6.25	1,050,000	2.80	
\$ 4.00	8,750,000	4.53	
	<u>18,570,847</u>	3.62	\$ 4.54

NOTE 6 – LEGAL PROCEEDINGS

The Company is not currently a party to any pending legal proceedings, material or otherwise. There are no legal proceedings to which any property of the Company is subject.

NOTE 7 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the three and six months ended October 31, 2023 and 2022, respectively.

The Company owns 14.3% of the equity in SG Austria and is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand. The Company purchased products and services from these subsidiaries in the approximate amounts of \$0 and \$4,700 in the three months ended October 31, 2023 and 2022, respectively, and \$0 and \$64,000 for the six months ended October 31, 2023 and 2022, respectively.

In April 2014, the Company entered the Vin-de-Bona Consulting Agreement pursuant to which it agreed to provide professional consulting services to the Company. Vin-de-Bona is owned by Prof. Günzburg and Dr. Salmons, both of whom are involved in numerous aspects of the Company's scientific endeavors relating to cancer and diabetes (Prof. Günzburg is the Chairman of Austrianova, and Dr. Salmons is the Chief Executive Officer and President of Austrianova). The term of the agreement is for 12 months and is automatically renewable for successive 12-month terms. After the initial term, either party can terminate the agreement by giving the other party 30 days' written notice before the effective date of termination. To date, the agreement has been automatically renewed annually. The amounts incurred for the three months ended October 31, 2023 and 2022, were approximately \$2,600 and \$2,400, respectively, and approximately \$2,700 and \$47,500 for the six months ended October 31, 2023 and 2022, respectively.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company acquires assets still in development and enters R&D arrangements with third parties that often require milestone and royalty payments to the third-party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development lifecycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the license agreements, the Company may have to make royalty payments based upon a percentage of the sales of the pharmaceutical products if regulatory approval for marketing is obtained.

Office Lease

In January 2022, the Company entered into a six-month lease of the Las Vegas, Nevada office space, commencing on May 1, 2022, which expired on October 31, 2022.

In July 2022, the Company entered into an additional six-month lease of the Las Vegas, Nevada office space, commencing on November 1, 2022, which expired on April 30, 2023.

In January 2023, the Company entered into a month-to-month agreement of the Las Vegas office space, commencing on May 1, 2023. Additionally, the Company rents storage space pursuant to a month-to-month agreement in Laguna Hills, California.

Rent expenses for the office for the three and six months ended October 31, 2023 were \$6,631 and \$15,598, respectively, and for the three and six months ended October 31, 2022 were \$5,760 and \$11,252, respectively.

With the month-to-month office rental agreements there are no aggregate future minimum lease payments required to be made.

Compensation Agreements

On January 1, 2022, the Company entered into an amended and restated executive compensation agreement with Carlos A. Trujillo, the Company's Chief Financial Officer. The compensation agreement for Mr. Trujillo has a term of three years, with automatic renewals unless the Company or Mr. Trujillo provides written notice of termination at least ninety days prior to the end of the current term.

As of October 31, 2023, the Company had five directors. Each non-employee director was entitled to receive \$12,500 in cash for each calendar quarter of service on the Board. Effective November 20, 2023, each non-employee director is entitled to receive \$15,000 each quarter of service on the Board, plus an additional \$2,500 quarterly for each non-employee director who serves as chair of the Board's audit committee, compensation committee or nominating and corporate governance committee.

On August 15, 2022, the Company and the Board: (i) accepted the previously tendered irrevocable resignation of each of Dr. Matthias Löhr, Dr. Raymond C.F. Tong, Thomas Liquard, Dr. Gerald W. Crabtree, and Carlos A. Trujillo, as members of the Board, and (ii) appointed Jonathan L. Schechter, Joshua N. Silverman, Daniel Allen, Daniel S. Farb, and Jack E. Stover as independent members of the Board, effective immediately, each with a term expiring at the Company's 2022 annual meeting of shareholders or until such person's earlier death, resignation, disqualification or removal.

On November 1, 2022, Jack E. Stover notified the Company of his decision to resign from the Board effective immediately. On November 14, 2022, in accordance with the recommendation of the Company's Nominating Committee, Robert Weinstein was appointed to serve as a director of the Board and the Chairperson of the Audit Committee, with a term expiring at the Company's annual meeting of shareholders or until death, resignation, disqualification or removal.

On November 14, 2022, the Board approved the employment of Mr. Joshua Silverman as the Interim Chief Executive Officer, Interim President and Interim Chairman of the Board on a month-to-month basis. Upon Mr. Silverman accepting employment he was no longer an independent director.

On December 28, 2022, the Company held its annual meeting of stockholders. The stockholders voted to elect the following directors to serve one-year terms expiring at the annual meeting of stockholders to be held during the year ended April 30, 2024: Joshua N. Silverman, Jonathan L. Schechter, Michael M. Abecassis, Robert Weinstein and Wayne R. Walker.

Service Agreements

The Company has entered into several service agreements with independent and related parties pursuant to which services will be provided over a specified period-of-time related to the IND which the FDA has placed on clinical hold. The services include regulatory affairs strategy, advice and follow up work on the IND and services related to having the clinical hold lifted. The total cost is estimated to be approximately \$392,000, of which the related party (SG Austria and its subsidiaries) portion will be approximately \$157,000. These amounts take into account some of the cost associated with the work and preclinical studies required to lift the clinical hold.

NOTE 9 – INCOME TAXES

At October 31, 2023, the Company had federal and state net operating loss carryforwards of approximately \$57,154,000 and \$48,945,000, respectively, available to offset against future taxable income; these operating loss carryforwards expire in 2023 through 2038. Internal Revenue Code Section 382 imposes an annual limitation for the utilization of tax attributes if there is an “ownership change”. Based upon the equity activity during the year ended April 30, 2022, the Company had an ownership change in August 2021. As a result of the change in-control that occurred in the Company’s shareholder base in August 2021, approximately \$37,060,000 and \$40,808,000 federal and state net operating loss carryforwards, respectively, became limited in their availability. The remaining net operating loss carryforwards are approximately \$20,094,000 and \$8,137,000 for federal and state purposes, respectively. The remaining net operating loss deferred tax assets are approximately \$4,220,000 and \$696,000 for federal and state purposes, respectively.

Current tax laws limit the amount of loss available to be offset against future taxable income when a substantial change in ownership occurs. Therefore, the amount available to offset future taxable income may be limited. Based on the assessment of all available evidence including, but not limited to, the Company’s limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulations and healthcare reform initiatives and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these operating loss carryforwards will not be realized. Accordingly, 100% of the deferred tax valuation allowance has been recorded against these assets.

The Company’s policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of the six months ended October 31, 2023 and 2022, the Company had accrued no interest or penalties related to uncertain tax positions.

See Note 9 of Notes to the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K for the year ended April 30, 2023, for additional information regarding income taxes.

NOTE 10 – EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing earnings (loss) available to common stockholders by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares and potentially dilutive shares of common stock outstanding during the period increased to include the number of additional shares of common stock that would be outstanding if the potentially dilutive securities had been issued. Potential shares of common stock outstanding principally include preferred stock, stock options and warrants. During the three and six months ended October 31, 2023 and 2022, the Company incurred losses attributable to common stockholders. Accordingly, the effect of any common stock equivalent would be anti-dilutive during those periods and are not included in the calculation of diluted weighted average number of shares outstanding.

The table below sets forth the basic loss per share calculations:

	Three Months Ended October 31,	
	2023	2022
Net loss attributable to common stockholders	\$ (2,258,087)	\$ (1,880,507)
Basic and diluted weighted average number of shares outstanding	8,765,134	20,585,451
Basic and diluted loss per share	\$ (0.26)	\$ (0.09)

	Six Months Ended October 31,	
	2023	2022
Net loss attributable to common stockholders	\$ (9,033,266)	\$ (3,425,519)
Basic and diluted weighted average number of shares outstanding	10,683,514	20,742,383
Basic and diluted loss per share	\$ (0.85)	\$ (0.17)

The table below sets forth these potentially dilutive securities:

	Three and Six Months Ended October 31,	
	2023	2022
Excluded options	279,802	37,936
Excluded warrants	18,570,847	9,890,847
Series B convertible preferred stock	8,035,940	—
Total preferred stock, options and warrants	26,886,589	9,928,783

NOTE 11 – PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, with a par value of \$0.0001, of which 35,000 shares have been designated as “Series B Convertible Preferred Stock”. As of October 31, 2023 and 2022, there were 31,480 and zero shares issued and outstanding, respectively, and 3,520 and zero, shares, respectively, subject to redemption which are classified as Accrued Series B convertible preferred redemptions and dividends on the condensed consolidated balance sheet.

On May 10, 2023, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain accredited investors (the “Investors”), pursuant to which it agreed to sell to the Investors (i) an aggregate of 35,000 shares of the Company’s newly-designated Series B convertible preferred stock with a stated value of \$1,000 per share, initially convertible into up to 8,750,000 shares of the Company’s common stock, par value \$0.0001 per share at a conversion price of \$4.00 per share (the “Preferred Shares”), and (ii) warrants to acquire up to an aggregate of 8,750,000 shares of common stock (the “Warrants”) (collectively, the “Private Placement”).

The terms of the Preferred Shares are as set forth in a Certificate of Designations (the “Certificate of Designations”), which was filed with the Secretary of the State of Nevada on May 10, 2023. The Preferred Shares are convertible into common stock (the “Conversion Shares”) at the election of the holder at any time at an initial conversion price of \$4.00 (the “Conversion Price”). The Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of common stock, or securities convertible, exercisable or exchangeable for common stock, at a price below the then-applicable Conversion Price (subject to certain exceptions). The Company is required to settle the Preferred Shares in equal monthly installments, commencing on November 9, 2023. The amortization payments due upon such redemption are payable, at the Company’s election, in cash, or subject to certain limitations, in shares of common stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) a 20% discount to the average of the three lowest closing prices of the Company’s common stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the lower of \$0.556 and 20% of the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) on the date of receipt of Nasdaq Stockholder Approval (as defined below); provided that if the amount set forth in clause B is the lowest effective price, the Company will be required to pay the amortization payment in cash. The Company may require holders to convert their Preferred Shares into Conversion Shares if the closing price of the common stock exceeds \$6.00 per share for 20 consecutive trading days and the daily trading volume of the common stock exceeds 1,000,000 shares per day during the same period and certain equity conditions described in the Certificate of Designations are satisfied.

The holders of the Preferred Shares are entitled to dividends of 4% per annum, compounded monthly, which are payable in cash or shares of common stock at the Company's option, in accordance with the terms of the Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Certificate of Designations), the Preferred Shares will accrue dividends at the rate of 15% per annum. The holders of Preferred Shares have no voting rights on account of the Preferred Shares, other than with respect to certain matters affecting the rights of the Preferred Shares.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization payments using shares of common stock is subject to certain limitations set forth in the Certificate of Designations, including a limit on the number of shares that may be issued until the time, if any, that the Company's stockholders have approved the issuance of more than 19.9% of the Company's outstanding shares of common stock in accordance with Nasdaq listing standards (the "Nasdaq Stockholder Approval"). The Company received Nasdaq Stockholder Approval at its special meeting of stockholders held on August 31, 2023. Further, the Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of common stock issuable upon conversion of, or as part of any amortization payment under, the Certificate of Designations or Warrants.

The Certificate of Designations includes certain Triggering Events (as defined in the Certificate of Designations), including, among other things, the failure to file and maintain an effective registration statement covering the sale of the holder's securities registrable pursuant to a registration rights agreement entered into by the Company and the Investors simultaneously with the Purchase Agreement and the Company's failure to pay any amounts due to the holders of the Preferred Shares when due. In connection with a Triggering Event, each holder of Preferred Shares will be able to require the Company to redeem in cash any or all of the holder's Preferred Shares at a premium set forth in the Certificate of Designations.

The Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) an installment redemption upon an Equity Conditions Failure (as defined in the Certificate of Designation), and 2) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in the fair value of these features are recognized in the Condensed Consolidated Statements of Operations. The Company estimated the \$2.8 million fair value of the bifurcated embedded derivative at issuance using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's common stock of \$2.74 on the issuance date, estimated equity volatility of 55.0%, estimated traded volume volatility of 355.0%, the time to maturity of 1.50 years, a discounted market interest rate of 15.9%, a risk free rate of 4.3%, dividend rate of 4.0%, a penalty dividend rate of 15.0%, and probability of default of 27.0%. The fair value of the bifurcated derivative liability was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

The discount to the fair value is included as a reduction to the carrying value of the Preferred Shares. During the six months ended October 31, 2023, the Company recorded a total discount of approximately \$18.2 million upon issuance of the Preferred Shares, which was comprised of the issuance date fair value of the associated embedded derivative of approximately \$2.8 million, stock issuance costs of approximately \$1.3 million and the fair value of the Warrants of approximately \$14.1 million. It was deemed probable that the Preferred Shares will become redeemable, the Company accreted the Preferred Shares from inception to October 31, 2023, pursuant to ASC 480-10-S99-3A.

During the six months ended October 31, 2023, the Company recorded a gain of approximately \$1.3 million related to the change in fair value of the derivative liability, which is recorded in other income, net on the Condensed Consolidated Statements of Operations. The Company estimated the \$4.1 million fair value of the bifurcated embedded derivative at October 31, 2023 using a Monte Carlo simulation model, with the following inputs: the fair value of our common stock of \$2.12 on the valuation date, estimated equity volatility of 70.0%, estimated traded volume volatility of 270.0%, the time to maturity of 1.03 years, a discounted market interest rate of 17.2%, a risk free rate of 5.43%, dividend rate of 4.0%, a penalty dividend rate of 15.0%, probability of default of 27.0%, and instrument term elapsed of 31.2%

During the three and six months ended October 31, 2023, the Company provided installment notices to the holders for the November and December installments, which installments were elected by the Company to be redeemed for cash. As a result, the Company reclassified the proportion of the installment amounts that were not deferred by the holders, inclusive of accrued dividends and cash premium, to the Accrued Series B convertible preferred stock redemptions and dividends liability account on the Condensed Consolidated Balance Sheets, \$3,520,833 of the Preferred Shares and \$361,718 of accrued dividends for cash and accreted \$4,461,097 and \$7,733,130, respectively, of discount related to the Preferred Shares. During the three months ended October 31, 2023, the Company recognized a deemed dividend of \$212,719 related to the amounts owed in addition to dividends if amortization is paid in cash which is included in Preferred stock dividends on the condensed consolidated statement of operations.

As of October 31, 2023, the Company has reclassified a portion of the Preferred Shares to an accrued liability for the first two installment redemptions owed to investors in cash of \$4,095,271 which includes \$3,520,833 of the stated value of the Preferred Shares, \$354,377 of dividends payable, and \$220,060 of additional 6% cash premium pursuant to the terms of the Series B Preferred stock. The Company provided notice to the investors of their intent to redeem the first two installments in cash prior to October 31, 2023.

The Company has one share of preferred stock designated as “Series A Preferred Stock” as of October 31, 2023 and April 30, 2023, there were no shares of Series A Preferred Stock issued and outstanding.

The description of the Series A Preferred Stock below is qualified in its entirety by reference to the Company’s Articles of Incorporation, as amended.

The Series A Preferred Stock has the following features:

- There is one share of preferred stock designated as Series A Preferred Stock;
- The Series A Preferred Stock has a number of votes at any time equal to the number of votes then held by all other shareholders of the Company having a right to vote on any matter plus one. The Certificate of Designations that designated the terms of the Series A Preferred Stock cannot be amended without the consent of the holder of the Series A Preferred Stock;
- The Company may redeem the Series A Preferred Stock at any time for a redemption price of \$1.00 paid to the holder of the share of Series A Preferred Stock; and
- The Series A Preferred Stock has no rights of transfer, conversion, dividends, preferences upon liquidation or participation in any distributions to shareholders.

NOTE 12 – TREASURY STOCK

In May 2022, the Board authorized a share repurchase program to acquire its outstanding common stock for up to \$10 million. In January 2023, the Board authorized an additional share repurchase program to acquire up to an additional \$10 million of the Company’s outstanding common stock. In conjunction with the share repurchase programs, the Company selected a broker to repurchase shares on behalf of the Company. The amount of common stock repurchased on any given trading day is determined by a formula, which is based on the market price of the common stock and average daily volumes. Shares repurchased are held in treasury for general corporate purposes. The shares are treated as Treasury Stock using the cost method. During the three and six months ended October 31, 2023, the Company repurchased 78,109 additional shares under the repurchase program. As of October 31, 2023, the total number of shares repurchased pursuant to the repurchase programs was 4,886,207 shares at a total cost, including commissions and excise taxes of \$13,727,225. Repurchased shares are included in Treasury Stock in the accompanying Condensed Consolidated Balance Sheets. At October 31, 2023, \$6,272,775 remains available to repurchase the Company’s common stock pursuant to the share repurchase programs.

Tender Offer

On May 11, 2023, the Company commenced a tender offer, in accordance with Rule 13e-4 promulgated under the Securities Exchange Act of 1934, as amended, to purchase up to 7,750,000 shares of its common stock, par value \$0.0001 per share, at a price of \$3.25 per share. The tender offer expired one minute after 11:59 p.m. on June 9, 2023, and following such expiration the Company accepted for purchase a total of 8,085,879 shares at \$3.25 per share, including 335,879 shares that the Company elected to purchase pursuant to its right to purchase up to an additional 2% of its outstanding shares. The resultant aggregate purchase price was \$26,721,897, including excise tax, fees and expenses relating to the tender offer. These shares are treated as Treasury Stock using the cost method and are included as Treasury Stock in the accompanying Condensed Consolidated Balance Sheets, Statements of Convertible Preferred Stock and Stockholders’ Equity.

As of October 31, 2023, the total number of shares held in Treasury Stock is 12,972,086 shares at a total cost of \$40,449,123.

NOTE 13 – FAIR VALUE MEASUREMENTS

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the six months ended October 31, 2023. The carrying amounts of cash equivalents, other current assets, accounts payable and accrued expenses approximate their fair values at October 31, 2023 due to their short-term nature. The fair value of the bifurcated embedded derivative related to the convertible preferred stock was estimated using a Monte Carlo simulation model, which uses as inputs the fair value of the Company's common stock and guideline companies estimates for the equity volatility and traded volume volatility of our common stock, the time maturity of the convertible preferred stock, the risk-free interest rate for a period of time that approximates the time to maturity, dividend rate, a penalty dividend rate and the probability of default. The fair value of the warrant liability was estimated using the Black Scholes Merton Model which uses as inputs the following weighted average assumptions, as noted above: dividend yield, expected terms in years, equity volatility and risk-free rate.

Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported and reported at fair at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The estimated fair value of the warrant liability and bifurcated embedded derivative represent Level 3 measurements. The following table presents information about the Company's liabilities that are measured at fair value on a recurring basis at October 31, 2023, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	Level	October 31, 2023	April 30, 2023
Liabilities:			
Warrant liability (Note 5)	3	\$ 11,504,000	\$ –
Bifurcated embedded derivative (Note 11)	3	\$ 4,069,000	\$ –

The following table sets forth a summary of the change in the fair value of the warrant liability that is measured at fair value on a recurring basis.

	October 31, 2023
Balance on April 30, 2023	\$ –
Issuance of warrants	14,127,000
Change in fair value of warrant liability	(2,623,000)
Balance on October 31, 2023	<u>\$ 11,504,000</u>

The following table sets forth a summary of the change in the fair value of the bifurcated embedded derivative liability that is measured on a recurring basis:

	October 31, 2023
Balance on April 30, 2023	\$ –
Issuance of convertible preferred stock with bifurcated embedded derivative liability	2,770,000
Change in fair value of bifurcated embedded derivative	1,299,000
Balance on October 31, 2023	<u>\$ 4,069,000</u>

NOTE 14 – SUBSEQUENT EVENTS

Securities Purchase Agreement

On November 14, 2023, the Company entered into a Securities Purchase Agreement (the “Femasys Purchase Agreement”) with Femasys (“Femasys”) pursuant to which the Company purchased (i) senior unsecured convertible notes in an aggregate principal amount of \$5 million, convertible into shares of Femasys common stock at a conversion price of \$1.18 per share, (ii) Series A warrants to purchase up to an aggregate of 4,237,288 shares of Femasys common stock at an exercise price of \$1.18 and (iii) Series B warrants to purchase an aggregate of 4,237,288 shares of Femasys common stock at an exercise price \$1.475 per share.

Cash and Stock Options Granted

On November 20, 2023, the Company’s Board approved (i) one-time cash grants to Joshua Silverman and Carlos Trujillo in the amounts of \$100,000 and \$50,000, respectively, and (ii) options to purchase up to 170,000 shares and 85,000 shares, respectively, at an exercise price of \$2.18 per share. The options vested 50% immediately, and the remaining 50% will vest on the one-year anniversary of the grant date.

On November 20, 2023, the Board granted to each non-employee director (i) a cash retainer fee of \$60,000 and (ii) options to purchase 61,248 shares at an exercise price of \$2.18 per share, vesting in full on the first business day after the Company’s next annual meeting of stockholders. Additionally, the Board granted each non-employee director who chairs the audit, compensation or nominating and corporate governance committees an additional cash retainer fee of \$10,000.

On November 20, 2023, the Board adopted a non-employee director compensation policy, which provides for the automatic annual grant of nonqualified stock options with a grant date fair value of \$60,000 to each non-employee director. Such grants shall occur annually on the first business day after the Company’s annual meeting of stockholders and shall vest on the one-year anniversary of the grant date, subject to the director’s continued service on the Board on the vesting date. The policy also provides for the payment of an annual \$60,000 cash retainer fee to each non-employee director, plus, for each non-employee director who chairs the audit, compensation or nominating and corporate governance committees, an additional annual \$10,000 cash retainer fee. Finally, the policy provides for the automatic grant of nonqualified stock options with a grant date fair value of \$50,000 to each new non-employee director upon joining the Board.

On November 20, 2023, the Company Board established a Strategic Scientific Committee. The committee will initially consist of two members. The Chair of the committee will be Dr. Michael Abecassis. Dr. Abecassis will receive a monthly retainer fee of \$3,500.

Stock Repurchase

From November 1, 2023 to December 13, 2023, the Company repurchased 84,352 shares of common stock through the stock repurchase program for \$187,363.

Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (including but not limited to this Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are intended to qualify for the "safe harbor" created by those sections. In addition, we may make forward-looking statements in other documents filed with or furnished to the Securities and Exchange Commission ("SEC"), and our management and other representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as "can", "may", "could", "should", "assume", "forecasts", "believe", "designed to", "will", "expect", "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "seek", "budget", "project" or "continue", or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, forward-looking statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and are subject to known and unknown risks, uncertainties and other factors. Accordingly, our actual results and the timing of certain events may differ materially from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth in this Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report, those set forth from time to time in our other filings with the U.S. Securities and Exchange Commission ("Commission"), including our Annual Report on Form 10-K for the fiscal year ended April 30, 2023 and the following factors and risks:

- As a result of the clinical hold that has been placed on our IND by the FDA, it has taken and may continue to take considerable time and expense to respond to the FDA, and no assurance can be given that the FDA will remove the clinical hold in which case our business and prospects will likely suffer material adverse consequences;
- We contract with Austrianova for the manufacture of our product candidates and for certain preclinical and clinical activities. Austrianova may not be able to manufacture sufficient quantities of our product candidates for preclinical studies and clinical trials which could delay, prevent or impair our development or commercialization efforts. The production of our product candidates relies in part on the proprietary know-how of Austrianova which is held by them as a trade secret and as to which we are not privy;
- We rely on officers of Austrianova for the development of our product candidates. If they decide to terminate their relationship with us, we may not be successful in the development of our product candidates;

- In the event Austrianova experiences financial difficulties, their ability to provide products or services to us may be delayed or curtailed and may affect the carrying value of our intellectual property and cost-based investment in Austrianova;
- At this time, we are unaware of any available substitute manufacturer other than Austrianova;
- We are seeking FDA approval to commence a clinical trial in the U.S. of our product candidate for LAPC based on clinical data that was obtained in trials conducted nearly 20 years ago outside the U.S., and it is possible that the FDA may not accept data from trials conducted in such locations or conducted nearly 20 years ago nor allow us to proceed with a Phase 2b as opposed to a Phase 1 or Phase 1/2 trial;
- The Business Review Committee and the Board are evaluating, investigating and reviewing our business, affairs, strategy, management and operations, including our development programs and our relationship with SG Austria (as defined below). There can be no guarantee that the Business Review Committee and the Board will be successful in achieving an acceptable new framework for our relationship with SG Austria, and if that is the case, we may need to reevaluate certain development programs. We have curtailed spending on our programs pending the review by the Business Review Committee and the Board, and delays caused by such curtailment may have an adverse effect on our business.
- Results in previous clinical trials of our encapsulated live cell and ifosfamide combination for pancreatic cancer may not be replicated in future clinical trials which could result in development delays or a failure to obtain marketing approval;
- Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- As the patents covering our Cell-in-a-Box technology have expired, our intellectual property, which is primarily trade secrets, and data and market exclusivity may not be sufficient to block others from commercializing identical or competing products; and
- We have experienced significant management changes which could increase our control risks and have a material adverse effect on our ability to do business and our results of operations.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- our expectations of future revenues, expenditures, capital or other funding requirements;
- the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory clearance or approval to market product candidates;
- the inherent uncertainties associated with commercialization of products that have received regulatory clearance or approval;
- economic and industry conditions generally and in our specific markets; and
- the volatility of, and decline in, our stock price.

All forward-looking statements and risk factors included in this Quarterly Report are made as of the date hereof, in each case based on information available to us as of the date hereof, and we assume no obligations to update any forward-looking statement or risk factor, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Forward-looking statements may include our plans and objectives for future operations, including plans and objectives relating to our product candidates and our future economic performance, projections, business strategy and timing and likelihood of success. Assumptions relating to the forward-looking statements included in this Quarterly Report involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our technologies, all of which are difficult or impossible to predict accurately and many of which are beyond our control.

Any of the assumptions underlying the forward-looking statements contained in this Quarterly Report could prove inaccurate and, therefore, we cannot assure you that any of the results or events contemplated in any of such forward-looking statements will be realized. Based on the significant uncertainties inherent in these forward-looking statements, the inclusion of any such statement should not be regarded as a representation or as a guarantee by us that our objectives or plans will be achieved, and we caution you against relying on any of the forward-looking statements contained herein.

Overview of Business

We are a biotechnology company focused on 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®.” The Cell-in-a-Box® technology is intended to be used as a platform upon which therapies for several types of cancer, including LAPC, will be developed. The current generation of our product candidate is referred to as “CypCaps™.”

On August 15, 2022, we entered into a Cooperation Agreement (the “Cooperation Agreement”) with Iroquois Master Fund Ltd. and its affiliates, pursuant to which we elected a reconstituted board of directors (the “Board”). The Board then formed a Business Review Committee to evaluate, investigate and review our business, affairs, strategy, management and operations and in its sole discretion, to make recommendations to our management and Board with respect thereto. The Business Review Committee is also reviewing many of the risks relative to our business. In addition, the Board is reviewing risks associated with our development programs and our relationship with SG Austria Pte. Ltd (“SG Austria”), including that all licensed patents have expired, that know-how relating to our Cell-in-a-Box® technology solely resides with SG Austria, and that the incentives of SG Austria and its management may not be currently aligned with ours. The Board has curtailed spending on our programs, including pre-clinical and clinical activities, until the review by the Business Review Committee and the Board is complete and the Board has determined the actions and plans to be implemented. The Business Review Committee’s recommendations will include potentially seeking a new framework for our relationship with SG Austria and its subsidiaries. If we are unsuccessful in seeking an acceptable new framework, we will reevaluate whether we should continue those programs which are dependent on SG Austria, including our development programs for locally advanced, inoperable, non-metastatic pancreatic cancer (“LAPC”), diabetes and malignant ascites. The issues involving SG Austria have delayed our timeline for addressing the FDA clinical hold for its planned clinical trial in LAPC and could result in other delays or termination of the development activities. In addition, the curtailment of spending on our programs pending the review by the Business Review Committee and the Board may cause additional delays.

The Cell-in-a-Box® encapsulation technology potentially enables genetically engineered live human cells to be used as a means to produce various biologically active molecules. The technology is intended to result in the formation of pinhead-sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In a laboratory setting, this proprietary live cell encapsulation technology has been shown to create a micro-environment in which encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors and passage through catheters and needles, which we believe enables greater cell growth and production of the active molecules. The capsules are largely composed of cellulose (cotton) and are bioinert.

We have been developing therapies for pancreatic and other solid cancerous tumors by using genetically engineered live human cells that we believe are capable of converting a cancer prodrug into its cancer-killing form. We encapsulate those cells using the Cell-in-a-Box[®] technology and place those capsules in the body as close as possible to the tumor. In this way, we believe that when a cancer prodrug is administered to a patient with a particular type of cancer that may be affected by the prodrug, the killing of the patient's cancerous tumor may be optimized.

We have also been developing a way to delay the production and accumulation of malignant ascites that results from many types of abdominal cancerous tumors. Our potential therapy for malignant ascites involves using the same encapsulated cells we employ for pancreatic cancer but placing the encapsulated cells in the peritoneal cavity of a patient and administering ifosfamide intravenously.

We have also been developing a potential therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. Our product candidate for the treatment of diabetes consists of encapsulated genetically modified insulin-producing cells. The encapsulation will be done using the Cell-in-a-Box[®] technology. Implanting these encapsulated cells in the body is designed to have them function as a bio-artificial pancreas for purposes of insulin production.

In addition to the two cancer programs discussed above, we have been working on ways to exploit the benefits of the Cell-in-a-Box[®] technology to develop therapies for cancer that involve prodrugs based upon certain constituents of the *Cannabis* plant. However, until the FDA allows us to commence our clinical trial in LAPC and we are able to validate our Cell-in-a-Box[®] encapsulation technology in a clinical trial, we are not spending any further resources developing our Cannabis Program.

Finally, we have been developing a potential therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. Our product candidate for the treatment of diabetes consists of encapsulated genetically modified insulin-producing cells. The encapsulation will be done using the Cell-in-a-Box[®] technology. Implanting these encapsulated cells in the body is designed to have them function as a bio-artificial pancreas for purposes of insulin production.

Until the Business Review Committee completes its evaluation of our programs and we enter into a new framework for its relationship with SG Austria, spending on our development programs has been curtailed.

Investigational New Drug Application and Clinical Hold

On September 1, 2020, we submitted an IND to the FDA for a planned clinical trial in LAPC. On October 1, 2020, we received notice from the FDA that it had placed our IND on clinical hold. On October 30, 2020, the FDA sent us a letter setting forth the reasons for the clinical hold and providing specific guidance on what we must do to have the clinical hold lifted.

In order to address the clinical hold, the FDA has requested that we:

- Provide additional sequencing data and genetic stability studies;
- Conduct a stability study on our final formulated product candidate as well as the cells from our Master Cell Bank ("MCB");
- Evaluate the compatibility of the delivery devices (the prefilled syringe and the microcatheter used to implant the CypCaps[™]) with our product candidate for pancreatic cancer;
- Provide additional detailed description of the manufacturing process of our product candidate for pancreatic cancer;
- Provide additional product release specifications for our encapsulated cells;

- Demonstrate comparability between the 1st and 2nd generation of our product candidate for pancreatic cancer and ensure adequate and consistent product performance and safety between the two generations;
- Conduct a biocompatibility assessment using the capsules material;
- Address specified insufficiencies in the Chemistry, Manufacturing and Controls information in the cross-referenced Drug Master File;
- Conduct an additional nonclinical study in a large animal (such as a pig) to assess the safety, activity, and distribution of the product candidate for pancreatic cancer; and
- Revise the Investigators Brochure to include any additional preclinical studies conducted in response to the clinical hold and remove any statements not supported by the data we generated.

The FDA also requested that we address the following issues as an amendment to our IND:

- Provide a Certificate of Analysis for pc3/2B1 plasmid that includes tests for assessing purity, safety, and potency;
- Perform qualification studies for the drug substance filling step to ensure that the product candidate for pancreatic cancer remains sterile and stable during the filling process;
- Submit an updated batch analysis for the product candidate for the specific lot that will be used for manufacturing all future product candidates;
- Provide additional details for the methodology for the Resorufin (CYP2B1) potency and the PrestoBlue cell metabolic assays;
- Provide a few examples of common microcatheters that fit the specifications in our Angiography Procedure Manual;
- Clarify the language in our Pharmacy Manual regarding proper use of the syringe fill with the product candidate for pancreatic cancer; and
- Provide a discussion with data for trial of the potential for cellular and humoral immune reactivity against the heterologous rat CYP2B1 protein and potential for induction of autoimmune-mediated toxicities in our study population.

We assembled a scientific and regulatory team of experts to address the FDA requests. That team has been working diligently to complete the items requested by the FDA. We are in the latter stages of conducting the studies and providing the information requested by the FDA. We have completed the pilot study of two pigs and are evaluating the preliminary data before it commences the larger study of 90 pigs.

The following provides a detailed summary of our activities to have the clinical hold lifted:

- Additional Regulatory Expertise Added to IND Team. In addition to our existing team of regulatory experts, we retained Biologics Consulting to perform a regulatory “Gap Analysis” and to assist us with our resubmission of the IND. Biologics Consulting is a full-service regulatory and product development consulting firm for biologics, pharmaceuticals and medical devices and has personnel with extensive FDA experience.
- Stability Studies on Our Clinical Trial Product Candidate for Pancreatic Cancer. We have successfully completed the required product stability studies. The timepoints were 3, 6, 9, 12, 18 and 24 months of our product candidate for pancreatic cancer being stored frozen at -80C. These studies included container closure integrity testing for certain timepoints.

- Additional Studies Requested by the FDA. We have successfully completed various additional studies requested by the FDA, including a stability study on the cells from our MCB used to make our CypCaps™. We are already at the 36-month stability timepoint for the cells from our MCB. We are also collating existing information on the reproducibility and quality of the filling of the MCB cells into vials ready for CypCaps™ manufacturing.
- Determination of the Exact Sequence of the Cytochrome P450 2B1 Gene. We have completed the determination of the exact sequence of the cytochrome P450 2B1 gene inserted at the site previously identified on chromosome 9 using state-of-the-art nanopore sequencing. This is a cutting edge, unique and scalable technology that permits real-time analysis of long DNA fragments. The result of this analysis of the sequence data confirmed that the genes are intact.
- Confirmation of the Exact Sequence of the Cytochrome P450 2B1 Gene Insert. An additional, more detailed analysis of the integration site of the cytochrome P450 2B1 gene from the augmented HEK293 cell clone that is used in our CypCaps™ was found to be intact. In this new study, we were able to confirm the previously determined structure of the integrated transgene sequence using more data points. These studies also set the stage for a next step analysis to determine the genetic stability of the cytochrome P450 2B1 gene at the DNA level after multiple rounds of cell growth. This new study has been completed in which our original Research Cell Bank (“RCB”) cells were compared with cells from the MCB. The analysis confirmed that the cytochrome P450 2B1 and the surrounding sequence has remained stable with no changes detected at the DNA level.
- Biocompatibility Studies. We have been involved with 10 biocompatibility studies requested by the FDA, eight of which have been completed successfully. The remaining studies are underway or about to start. The Acute Systemic Toxicity Study of Empty Cellulose Sulphate Capsules in Mice is underway. The Skin Sensitization Study of Empty Cellulose Sulphate Capsules in Guinea Pigs is about to start. These last two studies should be completed well before the pig study (see below) is completed. To enable the biocompatibility studies to be performed, we had Austrianova Singapore Pte. Ltd. (“Austrianova”) manufacture an additional 400 syringes of empty capsules.
- Systemic Toxicity Testing. We evaluated the potential toxicity of the capsule component of our product candidate for pancreatic cancer and determined there is no evidence of toxicity in any of the parameters examined. The study also confirmed previous data that shows our capsule material is bioinert.
- Micro-Compression and Swelling Testing. This testing is underway. We are developing and optimizing two reproducible methods for testing and confirming the physical stability and integrity of our CypCaps™ under extreme pressure. These studies required the acquisition of new equipment by Austrianova as well as validation and integration into Austrianova’s Quality Control laboratory.
- Break Force and Glide Testing. We are in the process of developing a protocol to measure whether the syringe, attached to the catheter when used to expel the capsules, will still have a break and glide force that is within the specifications we have established. We are setting the specifications based on the syringe/plunger manufacturer’s measured break and glide forces, or alternatively, accepted ranges for glide forces routinely used in the clinic.
- Capsules Compatibility with the Syringe and Other Components of the Microcatheter Delivery System. We are in the process of showing that CypCaps™ are not in any way adversely affected by the catheters used by interventional radiologists to deliver them into a patient. Compatibility data is being generated to demonstrate that the quality of the CypCaps™ is maintained after passage through the planned microcatheter systems.
- CypCaps Capsules and Cell Viability after Exposure to Contrast Medium. We have commenced testing to show that exposure of CypCaps™ to the contrast medium interventional radiologists used to implant the CypCaps™ in a patient has no adverse effect on CypCaps™. Contrast medium is used to visualize the blood vessels during implantation.
- Master Drug File Information. Austrianova is providing additional detailed confidential information on the manufacturing process, including information on the improvements and advancements made to our product candidate for pancreatic cancer since the last clinical trials were conducted with respect to reproducibility and safety. However, Austrianova has not changed the overall physical characteristics of CypCaps™ between the 1st and 2nd generations.

- Additional Documentation Requested by the FDA. We are in the process of updating our IND submission documentation, including our discussion on immunological aspects of our treatment for LAPC.
- Pig Study. We have commenced a study in pigs to address biocompatibility and long-term implantation and dispersion of CypCaps™. The study has two phases: (i) a pilot study with 2 pigs; and (ii) a 90-pig study. The first phase has been completed and we are evaluating preliminary data. We believe this study should complement the positive data already available from the previous human clinical trials showing the safety of CypCaps™ implantation in human patients. The second phase of the pig study may be delayed as a result of supply chain problems, production delays at Austrianova, and to our curtailment of spending pending review of our programs by the Business Review Committee and the reconstituted Board, including seeking a new framework for its relationship with SG Austria and its subsidiaries.

Performance Indicators

Non-financial performance indicators used by management to manage and assess how the business is progressing will include, but are not limited to, the ability to: (i) acquire appropriate funding for all aspects of our operations; (ii) acquire and complete necessary contracts; (iii) complete activities for producing genetically modified human cells and having them encapsulated for our preclinical studies and the planned clinical trial in LAPC; (iv) have regulatory work completed to enable studies and trials to be submitted to regulatory agencies; (v) complete all required tests and studies on the cells and capsules we plan to use in our clinical trial in patients with LAPC; (vi) ensure completion of the production of encapsulated cells according to cGMP regulations to use in our planned clinical trial; (vii) complete all of the tasks the FDA requires of us in order to have the clinical hold lifted; and (viii) obtain approval from the FDA to lift the clinical hold on our IND so that we may commence our clinical trial in LAPC.

There are numerous items required to be completed successfully to ensure our final product candidate is ready for use in our planned clinical trial in LAPC. The effects of material transactions with related parties, and certain other parties to the extent necessary for such an undertaking, may have substantial effects on both the timeliness and success of our current and prospective financial position and operating results. In addition, the review of our programs by our Business Review Committee and reconstituted Board and the curtailment of spending until their review is complete and recommendations are made may have an adverse effect on the timeliness and success of our programs. In addition, if we are unsuccessful in seeking a new framework for the Company's relationship with SG Austria and its subsidiaries, the Company will reevaluate whether it should continue those programs which are dependent on SG Austria, including its programs for LAPC, diabetes and malignant ascites. See "Overview of Business." We will assess these factors on a regular basis to provide accurate information to our shareholders.

Results of Operations

Three and six months ended October 31, 2023, compared to three and six months ended October 31, 2022

Revenue

We had no revenues for the three and six months ended October 31, 2023 and 2022.

Operating Expenses and Loss from Operations

The total operating expenses and loss from operations during the three months ended October 31, 2023, were \$1,409,520, a decrease of \$909,100 compared to the three months ended October 31, 2022. The decrease is mainly attributable to decreases in general and administrative costs net of an increase relating to warrant issuance costs of \$913,640, and in R&D costs, compensation expense and legal and professional expense costs, net of an increase in director fees in the three months ended October 31, 2023.

	Three Months Ended October 31, 2023	Change - Increase (Decrease) and Percent	Three Months Ended October 31, 2022
Operating expenses:			
R&D	\$ 82,033	\$ (95,963) (54%)	\$ 177,996
Compensation expense	\$ 229,159	\$ (171,261) (43%)	\$ 400,420
Director fees	\$ 306,738	\$ 204,403 200%	\$ 102,335
General and administrative, legal and professional	\$ 791,590	\$ (846,279) (52%)	\$ 1,637,869

The total operating expenses and loss from operations during the six months ended October 31, 2023, decreased by \$514,382 to \$3,484,846 compared to the six months ended October 31, 2022. The decrease is mainly attributable to decreases in R&D costs, compensation expense, legal and professional expense, and consulting expense in 2023 from 2022, net of an increase in general and administrative costs of \$1,200,207, including warrant issuance costs of \$913,640 and director fees of \$201,891.

	Six Months Ended October 31, 2023	Change - Increase (Decrease) and Percent	Six Months Ended October 31, 2022
Operating expenses:			
R&D	\$ 186,516	\$ (150,753) (45%)	\$ 337,269
Compensation expense	\$ 469,157	\$ (258,981) (36%)	\$ 728,138
Director fees	\$ 356,953	\$ 201,891 103%	\$ 155,062
General and administrative, legal and professional	\$ 2,472,220	\$ (306,539) (11%)	\$ 2,778,759

Other Income (Expenses), Net

Other income (expenses), net for the three months ended October 31, 2023 was \$4,199,416 as compared to other income (expenses), net of \$438,113 for the three months ended October 31, 2022. Other income (expenses), net for the three months ended October 31, 2023 is attributable to interest income of \$894,181 net of changes in fair value of warrant liability of \$4,075,000, a change in fair value of derivative liability of \$(769,000) and other expenses of \$(765). Other income, net for the three months ended October 31, 2022 is attributable to interest income of \$439,171 net of other expenses of \$(1,058). The increase in interest income is attributable to an increase in the rates of interest.

Other income (expenses), net, for the six months ended October 31, 2023 was \$3,091,445 as compared to other income (expenses), net of \$573,709 for the six months ended October 31, 2022. Other income (expenses), net for the six months ended October 31, 2023 is attributable to interest income of \$1,770,059 net of changes in fair value of warrant liability of \$2,623,000, a change in fair value of derivative liability of \$(1,299,000) and other expenses of \$(2,614). Other income, net for the six months ended October 31, 2022 is attributable to interest income of \$578,673 net of other expenses of \$(4,964). The increase in interest income is attributable to an increase in the rates of interest.

Discussion of Operating, Investing and Financing Activities

The following table presents a summary of our sources and uses of cash for the six months ended October 31, 2023 and 2022.

	Six Months Ended October 31, 2023	Six Months Ended October 31, 2022
Net cash used in operating activities:	\$ (1,641,395)	\$ (2,963,642)
Net cash used in investing activities:	\$ —	\$ —
Net cash provided by (used in) financing activities:	\$ 7,027,868	\$ (5,475,011)
Effect of currency rate exchange	\$ (1,140)	\$ 584
Net increase (decrease) in cash and cash equivalents	\$ 5,385,333	\$ (8,438,069)

Operating Activities:

The cash and cash equivalents used in operating activities for the six months ended October 31, 2023 is a result of our net losses and offset by the change in fair value of warrant liability of \$2,623,000 offset by the change in the fair value of the derivative liability of \$1,299,000, and changes to prepaid expenses, accounts payable, accrued expenses, and accrued dividends totaling approximately \$342,000. The cash and cash equivalents used in operating activities for the six months ended October 31, 2022 is a result of our net losses offset by securities issued for services and compensation of approximately \$18,000 and changes to prepaid expenses, accounts payable and accrued expenses of approximately \$444,000.

Investing Activities:

We had no investing activities for the six months ended October 31, 2023 and 2022.

Financing Activities:

The cash and cash equivalents provided by in financing activities for the six months ended October 31, 2023 is mainly attributable to the repurchase of common stock of approximately \$26,622,277 and net of the proceeds from the issuance of preferred stock of approximately \$32,736,000, net of issuance costs.

Liquidity and Capital Resources

As of October 31, 2023, our cash and cash equivalents totaled approximately \$73 million, compared to approximately \$77 million as of October 31, 2022. Working capital was approximately \$68 million as of October 31, 2023, compared to approximately \$76 million as of October 31, 2022. The increase in cash for the six months ended October 31, 2023 is attributable to a decrease in our operating expenses of approximately \$0.5 million and the repurchase of our common stock of approximately \$27 million, net of proceeds from the issuance of preferred stock and warrants of \$34 million.

On May 10, 2023, we entered into the Purchase Agreement, pursuant to which we sold to the Investors 35,000 Preferred Shares and Warrants to acquire up to an aggregate of 8,750,000 shares of common stock. The gross proceeds of the Private Placement were \$35 million, before offering expenses. If all of the Warrants were exercised for cash, we would receive additional gross proceeds of approximately \$35 million.

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships, collaborations and sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of pharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. Our future capital requirements are difficult to forecast and will depend on many factors, but we believe that our cash on hand will enable us to fund operating expenses for at least the next 12 months following the issuance of our financial statements.

On November 14, 2023, we entered into the Femasys Purchase Agreement. Pursuant to the agreement we agreed to purchase (i) senior unsecured convertible notes in an aggregate principal amount of \$5 million, convertible into shares of Femasys common stock at a conversion price of \$1.18 per share, and (ii) Series A warrants to purchase up to an aggregate of 4,237,288 shares of Femasys common stock at an exercise price of \$1.18 and (iii) Series B warrants to purchase an aggregate of 4,237,288 shares of Femasys common stock at an exercise price \$1.475 per share.

On November 20, 2023, the Board granted to each non-employee director (i) a cash retainer fee of \$60,000 and (ii) options to purchase 61,248 shares at an exercise price of \$2.18 per share, vesting in full on the first business day after the Company's next annual meeting of stockholders. Additionally, the Board granted each non-employee director who chairs the audit, compensation or nominating and corporate governance committees an additional cash retainer fee of \$10,000.

On November 20, 2023, the Board adopted a non-employee director compensation policy, which provides for the automatic annual grant of nonqualified stock options with a grant date fair value of \$60,000 to each non-employee director. Such grants shall occur annually on the first business day after the Company's annual meeting of stockholders and shall vest on the one-year anniversary of the grant date, subject to the director's continued service on the Board on the vesting date. The policy also provides for the payment of an annual \$60,000 cash retainer fee to each non-employee director, plus, for each non-employee director who chairs the audit, compensation or nominating and corporate governance committees, an additional annual \$10,000 cash retainer fee. Finally, the policy provides for the automatic grant of nonqualified stock options with a grant date fair value of \$50,000 to each new non-employee director upon joining the Board.

On November 20, 2023, our Board established a Strategic Scientific Committee. The committee will initially consist of two members. The Chair of the committee will be Dr. Michael Abecassis. Dr. Abecassis will receive a monthly retainer fee of \$3,500.

Service Agreements

We entered into several service agreements, with both independent and related parties, pursuant to which services will be provided over the next twelve months related to the clinical hold on our IND submission involving LAPC. The services include developing studies and strategies relating to clearing the clinical hold. The total cost is estimated to be approximately \$392,000, of which the related party portion will be approximately \$157,000. These agreements are under review by our Business Review Committee and reconstituted Board which has curtailed spending on this program until their review is complete and recommendations are made.

Critical Accounting Estimates and Policies

Our financial statements are prepared in accordance with U.S. GAAP. We are required to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the related disclosures. We base our assumptions, estimates and judgments on historical experience, current trends and other factors that management believes to be relevant at the time our financial statements are prepared. On a regular basis, management reviews the accounting policies, assumptions, estimates and judgments to ensure that our financial statements are presented fairly and in accordance with U.S. GAAP. However, because future events and their effects cannot be determined with certainty, actual results could differ from our assumptions and estimates, and such differences could be material.

Our significant accounting policies are discussed in Note 2 of the Notes to our Condensed Consolidated Financial Statements contained in this Quarterly Report. Management believes that the accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results and require management's most difficult, subjective or complex judgments resulting from the need to make estimates about the effects of matters that are inherently uncertain. Management has reviewed these critical accounting estimates and related disclosures with our Board.

Realizable Value of Intangible Assets and Investments

We test the carrying amount of our indefinite-lived intangible assets for impairment prior to testing long-lived assets for impairment. As prescribed under ASC 350, we first assess qualitative factors to determine whether events and circumstances indicate that it is more likely than not (that is, a likelihood of more than 50%) that our indefinite-lived intangible asset is impaired. If it is more likely than not that the asset is impaired, we would calculate the fair value of the asset and record an impairment charge if the carrying amount exceeds fair value. If we determine that it is not more likely than not that the asset is impaired, no further action is required.

Warrant liabilities

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, or date of modification, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The fair value of the warrant liability was estimated using a Black Scholes valuation approach with assumption relevant as of the valuation date.

Derivative Financial Instruments

The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the statement of operations each period. Bifurcated embedded derivatives are classified with the related host contract in the Company's balance sheet.

Preferred Stock

In accordance with ASC 480, the Company's Series B Preferred Stock is classified as temporary equity as it is redeemable upon certain contingent events that are considered outside of the Company's control. Further, in accordance with ASC 815-40, *Derivatives and Hedging – Contracts in an Entity's Own Equity*, the Series B Preferred Stock does not meet any of the criteria that would preclude equity classification. The stock discount is amortized from the date of issuance using the effective interest method.

Net Income (Loss) Per Share

Basic net income (loss) per share of common stock is computed using the weighted-average number of shares of common stock outstanding. Diluted net income (loss) per share of common stock is computed using the weighted-average number of shares of common stock and shares of common stock equivalents outstanding.

New Accounting Pronouncements

For a discussion of all recently adopted and recently issued but not yet adopted accounting pronouncements, see Note 2 "Summary of Significant Accounting Policies" of the Notes to our Condensed Consolidated Financial Statements contained in this Quarterly Report.

Available Information

Our website is located at www.PharmaCyte.com. In addition, all our filings submitted to the Commission, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all our other reports and statements filed with the Commission are available on the Commission's web site at www.sec.gov. Such filings are also available for download free of charge on our website. The contents of the website are not, and are not intended to be, incorporated by reference into this Quarterly Report or any other report or document filed with the Commission or furnished by us, and any reference to the websites are intended to be inactive textual references only.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The information called for by Item 3 is not required for a smaller reporting company.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Interim Chairman, Interim Chief Executive Officer, and Interim President, as our principal executive officer (“Chief Executive Officer”), and our Chief Financial Officer, as our principal financial officer (“Chief Financial Officer”), evaluated the effectiveness of our “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act. Disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or submit to the Commission pursuant to the Exchange Act are recorded, processed, summarized and reported within the period specified by the Commission’s rules and forms and are accumulated and communicated to our management, including our Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosures. Based upon this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of October 31, 2023, certain of our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting.

Reference should be made to our Form 10-K filed with the Commission on July 31, 2023, for additional information regarding discussion of the effectiveness of the Company’s control and procedures.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Also, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Changes in Internal Controls over Financial Reporting

There were no changes to our internal control over financial reporting during the six months ended October 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

In connection with the October 31, 2023 reporting process, management identified a material weakness related to the Company’s lack of a sufficient number of accounting personnel with the appropriate level of technical knowledge, experience and training in U.S. generally accepted accounting practices (GAAP) and SEC reporting requirements.

The Certifications of our Chief Executive Officer and Chief Financial Officer required in accordance with Rule 13a-14(a) under the Exchange Act and Section 302 of the Sarbanes-Oxley Act of 2002 (“Certifications”) are attached to this Quarterly Report. The disclosures set forth in this Item 4 contain information concerning: (i) the evaluation of our disclosure controls and procedures, and changes in internal control over financial reporting, referred to in paragraph 4 of the Certifications; and (ii) material weaknesses in the design or operation of our internal control over financial reporting, referred to in paragraph 5 of the Certifications. The Certifications should be read in conjunction with this Item 4 for a more complete understanding of the matters covered by the Certifications.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

There is no material litigation currently pending against us or any of our subsidiaries or to which any of our or our subsidiaries' property is subject. To our knowledge, there is no material litigation against any of our officers or directors in their capacity as such, and no such litigation is contemplated by any governmental authorities.

Item 1A. Risk Factors.

The information called for by Item 1A is not required for a smaller reporting company. In addition to the other information set forth in this Quarterly Report, you should carefully consider the factors discussed in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K of the Company filed with the Commission on July 31, 2023.

Other than as set forth below, there have been no material changes to the risk factors previously reported in our Annual Report on Form 10-K of the Company filed with the Commission on July 28, 2022.

Any weakness in our internal controls could have a material adverse effect on us.

The senior management has identified material weaknesses in our internal controls over financial reporting and cannot assure you that additional material weaknesses will not be identified in the future. We cannot assure you that these steps will be successful in preventing material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. In addition, any such failure could adversely affect our ability to report financial results on a timely and accurate basis, which could have other material effects on our business, reputation, results of operations, financial condition or liquidity. Material weaknesses in internal controls over financial reporting or disclosure controls and procedures could also cause investors to lose confidence in our reported financial information which could have an adverse effect on the trading price of our securities.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the three-months ended October 31, 2023, there were no shares issued.

Issuer Purchases of Equity Securities

The table below summarizes information about the Company's purchases of its equity securities during the quarterly period ended October 31, 2023.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under the Plans or Programs
August 1, 2023 – August 31, 2023	–	\$ –	–	\$ 6,439,377
September 1, 2023 – September 30, 2023	–	\$ –	–	\$ 6,439,377
October 1, 2023 - October 31, 2023	78,109	\$ 2.1329	78,109	\$ 6,272,775
October 31, 2023	78,109	\$ 2.1329	78,109	\$ 6,272,775

On June 2, 2022, the Company announced that the Board had authorized a share repurchase program to acquire up to \$10 million of the Company's outstanding common stock (the "Original Program"). The number of shares of common stock repurchased on any given trading day is determined by a formula, which is based on the market price of the common stock and average daily volumes. The Repurchase Program expires on May 30, 2024. On January 31, 2023, the Board authorized a share repurchase program to repurchase up to an additional \$10 million of the Company's outstanding common stock (the "New Program" and together with the Original Program, the "Repurchase Programs"). Under the New Program, the shares may be repurchased from time to time in open market transactions, privately negotiated block transactions or other means in accordance with applicable securities laws. During the three months ended October 31, 2023, the Company repurchased 78,109 shares pursuant to the Repurchase Programs. For more information on the Repurchase Programs, see "Note 12 – Treasury Stock."

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosure.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Description	Location
3.1	Certificate of Change to Articles of Incorporation of the Company, dated September 6, 2023	Incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed on September 7, 2023
31.1	Principal Executive Officer Certification required by Rules 13a-14 and 15d-14 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Principal Financial Officer Certification required by Rules 13a-14 and 15d-14 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of 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 Sarbanes Oxley Act of 2002	Furnished herewith
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	
104	Cover Page Interactive Data File (formatted in Inline XBRL and included in exhibit 101).	

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned thereunto duly authorized.

PharmaCyte Biotech, Inc.

December 15, 2023

By: /s/ Joshua N. Silverman
Joshua N. Silverman
Interim Chief Executive Officer
(Principal Executive Officer)

December 15, 2023

By: /s/ Carlos A. Trujillo
Carlos A. Trujillo
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13A-14(A) AND 15D-15(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joshua N. Silverman, certify that:

1. I have reviewed the Quarterly Report on Form 10-Q of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the period ended October 31, 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 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: December 15, 2023

By: /s/ Joshua N. Silverman
Name: Joshua N. Silverman
Title: Interim Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13A-14(A) AND 15D-15(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Carlos A. Trujillo, certify that:

1. I have reviewed the Quarterly Report on Form 10-Q of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the period ended October 31, 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 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: December 15, 2023

By: /s/ Carlos A. Trujillo
Name: Carlos A. Trujillo
Title: Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

**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 Quarterly Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-Q for the period ended October 31, 2023 as filed with the United States Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Joshua N. Silverman, the Chief Executive Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Dated: December 15, 2023

By: /s/ Joshua N. Silverman
Name: Joshua N. Silverman
Title: Interim Chief Executive Officer
(Principal Executive Officer)

This exhibit shall not be deemed "filed" with the Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing; however, it is instead furnished as provided by applicable rules of the Commission.

**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 Quarterly Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-Q for the period ended October 31, 2023 as filed with the United States Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Carlos A. Trujillo, the Chief Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Dated: December 15, 2023

By: /s/ Carlos A. Trujillo
Name: Carlos A. Trujillo
Title: Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

This exhibit shall not be deemed "filed" with the Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing; however, it is instead furnished as provided by applicable rules of the Commission.