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

FORM 10-Q

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

For the quarterly period ended July 31, 2022

or

o 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	**62-1772151**
(State or other jurisdiction of incorporation or organization)	(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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 September 14, 2022, the registrant had 20,750,068 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
FOR THE THREE MONTHS ENDED JULY 31, 2022

PART I – FINANCIAL INFORMATION

Item 1. Financial Information.

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

	July 31, 2022	April 30, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,227,615	$ 85,400,656
Prepaid expenses and other current assets	28,148	94,172
Total current assets	82,255,763	85,494,828
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	$ 87,385,071	$ 90,624,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 559,026	$ 205,361
Accrued expenses	530,331	499,009
Total current liabilities	1,089,357	704,370
Total Liabilities	1,089,357	704,370
Commitments and Contingencies (Notes 7 and 9)	–	–
Stockholders' equity:		
Common stock, authorized: 33,333,334 shares, $0.0001 par value; shares issued 21,602,049, shares outstanding 20,750,068 as of July 31, 2022, and 20,721,047 shares issued and outstanding as of April 30, 2022, respectively	2,160	2,072
Additional paid-in capital	201,592,522	201,582,107
Accumulated deficit	(113,193,668)	(111,648,656)
Treasury stock, at cost, 851,981 shares as of July 31, 2022	(2,090,847)	–
Accumulated other comprehensive loss	(14,453)	(15,757)
Total stockholders' equity	86,295,714	89,919,766
Total Liabilities and Stockholders' Equity	$ 87,385,071	$ 90,624,136

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended July 31,	
	2022	**2021**
Revenue	$ –	$ –
Operating expenses:		
Research and development costs	159,273	143,613
Compensation expense	327,718	268,885
Director fees	52,727	63,159
Legal and professional	896,221	185,748
General and administrative	244,669	361,946
Total operating expenses	1,680,608	1,023,351
Loss from operations	(1,680,608)	(1,023,351)
Other income (expense):		
Interest income	139,502	–
Interest expense	–	(467)
Other expense	(3,906)	(1,600)
Total other income (expense), net	135,596	(2,067)
Net loss	$ (1,545,012)	$ (1,025,418)
Basic loss per share	$ (0.07)	$ (0.64)
Diluted loss per share	$ (0.07)	$ (0.64)
Weighted average shares outstanding basic	20,829,315	1,591,306
Weighted average shares outstanding diluted	20,829,315	1,591,306

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended July 31,	
	2022	**2021**
Net loss	$ (1,545,012)	$ (1,025,418)
Other comprehensive income (loss):		
Foreign currency translation adjustment	1,304	(1,615)
Other comprehensive income (loss)	1,304	(1,615)
Comprehensive loss	$ (1,543,708)	$ (1,027,033)

See accompanying Notes to Condensed Consolidated Financial Statements.

PHARMACYTE BIOTECH, INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
THREE MONTHS ENDED JULY 31, 2022 AND 2021
(UNAUDITED)

	Common Stock		Additional Paid-in	Treasury Stock		Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Loss	Equity
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
Balance, April 30, 2021	1,590,084	$ 159	$ 114,109,169	–	–	$ (107,409,495)	$ (20,382)	$ 6,679,451
Stock issued for compensation	–	–	11,055	–	–	–	–	11,055
Stock issued for services	1,336	–	24,765	–	–	–	–	24,765
Stock issued for cash, net of issuance costs of $194,150	20,251	2	(2)	–	–	–	–	–
Stock-based compensation options	–	–	24,144	–	–	–	–	24,144
Foreign currency translation adjustment	–	–	–	–	–	–	(1,615)	(1,615)
Net loss	–	–	–	–	–	(1,025,418)	–	(1,025,418)
Balance, July 31, 2021	1,611,671	$ 161	$ 114,169,131	–	$ –	$ (108,434,913)	$ (21,997)	$ 5,712,382

See accompanying Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended July 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (1,545,012)	$ (1,025,418)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	2,278	24,765
Stock issued for compensation	2,750	11,055
Stock-based compensation – options	4,595	24,144
Change in assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	66,024	(246,930)
Increase (decrease) in accounts payable	353,665	(6,519)
Increase (decrease) in accrued expenses	31,322	(22,318)
Net cash used in operating activities	(1,084,378)	(1,241,221)
Cash flows from investing activities:		
Net cash provided by (used in) investing activities	–	–
Cash flows from financing activities:		
Repurchase of common stock	(2,090,847)	–
Proceeds from warrant exercise	880	–
Net cash used in financing activities	(2,089,967)	–
Effect of currency rate exchange on cash and cash equivalents	1,304	(1,615)
Net decrease in cash and cash equivalents	(3,173,041)	(1,242,836)
Cash and cash equivalents at beginning of the period	85,400,656	2,202,106
Cash and cash equivalents at end of the period	$ 82,227,615	$ 959,270
Supplemental disclosure of cash flows information:		
Cash paid during the periods for income taxes	$ –	$ 1,600
Cash paid during the periods for interest	$ –	$ 467
Supplemental information of non-cash activities:		
Prepaid expenses included in accounts payable	$ –	$ 229,033

See accompanying Notes to Condensed Consolidated Financial Statements.

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 to treat cancer and 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 has 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. See Note 13 – Subsequent Events to the Notes to Condensed Consolidated Financial Statements. 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 that this 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 in the latter stages of conducting the studies and providing the information requested by the FDA. The Company has completed the pilot study of two pigs and is evaluating the preliminary data before commencing the larger study of 90 pigs.

Impact of COVID-19 on the Company's Financial Condition and Results of Operations

The coronavirus SARS Cov2 pandemic ("COVID-19") continues to cause uncertainty and significant, industry-wide delays in clinical trials. The availability of vaccines holds promise for the future; however, new variants of the virus and potential waning immunity from vaccines may result in continued impact from COVID-19 in the future, which could adversely impact our operations. Although the Company is not yet in a clinical trial, the Company has filed an IND with the FDA to commence a clinical trial in LAPC. While the IND has been placed on clinical hold by the FDA, the Company has assessed the impact of COVID-19 on its operations.

Many clinical trials have been delayed due to COVID-19. There are numerous reasons for these delays. For example, patients have shown a reluctance to enroll or continue in a clinical trial due to fear of exposure to COVID-19 when they are in a hospital or doctor's office. There are local, regional and state-wide orders and regulations restricting usual normal activity by people. These discourage and interfere with patient visits to a doctor's office if the visit is not COVID-19 related. Healthcare providers and health systems have shifted their resources away from clinical trials toward the care of COVID-19 patients. The FDA and other healthcare providers are making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to COVID-19.

As a result of COVID-19 and the mitigation efforts to address it, the Company may experience additional disruptions that could adversely impact its business and clinical trial, if allowed to proceed, including: (i) delays or difficulties in enrolling patients in the Company's clinical trial if the FDA allows the Company to go forward with the trial; (ii) delays or difficulties in clinical site activation, including difficulties in recruiting clinical site investigators and clinical site personnel; (iii) delays in clinical sites receiving the supplies and materials needed to conduct the clinical trial, including interruption in global shipping that may affect the transport of the Company's clinical trial product; (iv) changes in local regulations as part of a response to COVID-19 which may require the Company to change the ways in which its clinical trial is to be conducted, which may result in unexpected costs, or to discontinue the clinical trial altogether; (v) diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as the Company's clinical trial sites and hospital staff supporting the conduct of the Company's clinical trial; (vi) interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; (vii) risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; (viii) delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; (ix) limitations in employee resources that would otherwise be focused on the conduct of the Company's clinical trial because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; (x) refusal of the FDA to accept data from clinical trials in affected geographies; and (xi) interruption or delays to the Company's clinical trial activities.

As a result of COVID-19, commencement of the Company's clinical trial to treat LAPC may be delayed beyond the lifting of the clinical hold by the FDA should that occur. Also, enrollment may be difficult for the reasons discussed above. In addition, after enrollment in the trial, if patients contract COVID-19 during their participation in the trial or are subject to isolation or shelter in place restrictions, this may cause them to drop out of our clinical trial, miss scheduled therapy appointments or follow-up visits or otherwise fail to follow the clinical trial protocol. If patients are unable to follow the clinical trial protocol or if the trial results are otherwise affected by the consequences of COVID-19 on patient participation or actions taken to mitigate COVID-19 spread, the integrity of data from the clinical trial may be compromised or not be accepted by the FDA. This could further adversely impact or delay the Company's clinical development program if the FDA allows it to proceed.

Clinical trials in the biopharma industry may be delayed due to COVID-19. There are numerous reasons for these potential delays. The impact relates to delays in: (i) completing studies required by the FDA; (ii) manufacturing a new batch of CypCap™ for the Company's planned clinical trial in LAPC; (iii) manufacturing syringes of CypCaps™ for some of the Company's preclinical studies to be completed and for use in the Company's Malignant Ascites Program; and (iv) securing third party contractors to conduct various R&D projects for the Company. As a result, there may be delays in generating responses to the requests from the FDA related to the clinical hold. Many of these potential delays are also due to the impact of COVID-19 in foreign countries where the Company is conducting these preclinical studies, including India, Europe, Singapore and Thailand. There have also been supply chain interruptions due to COVID-19.

It is highly speculative in projecting the effects of COVID-19 on the Company's proposed clinical development program and the Company generally. Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The continuation of COVID-19 could materially disrupt the Company's business and operations, hamper its ability to raise additional funds or sell securities, continue to slow down the overall economy, curtail consumer spending, interrupt the Company's sources of supply, and make it hard to adequately staff the Company's operations. The effects of COVID-19 quickly and dramatically change over time. Its evolution is difficult to predict, and no one is able to say with certainty when the pandemic will fully cease to have an impact on the Company's operations.

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."

Reverse Stock Split

Effective July 12, 2021, the Company filed a Certificate of Change with the Nevada Secretary of State that authorized a 1:1500 reverse stock split of the Company's common stock. The reverse stock split resulted in reducing the authorized number of shares of the Company's common stock from 50 billion to thirty-three million three hundred thirty-three thousand three hundred thirty-four with a par value of $0.0001 per share. Any fractional shares resulting from the reverse stock split were rounded up to the next whole share. All warrants, option, share and per share information in this Report gives retroactive effect to such 1:1500 reverse stock split.

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) Bio Blue Bird; (ii) PharmaCyte Biotech Europe Limited; (iii) PharmaCyte Biotech Australia Pty. Ltd.; and (iv) Viridis Biotech, Inc. and are prepared in accordance with 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 on the cost method of accounting.

Use of Estimates in the Preparation of Financial Statements

The Condensed Consolidated Financial Statements are prepared in accordance with U.S. generally accepted accounting principles ("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 consolidated financial position and results of operations. The severity, magnitude and duration, as well as the economic consequences of COVID-19, are uncertain, rapidly changing and difficult to predict. Therefore, the Company's accounting estimates and assumptions may change over time in response to COVID-19 and may change materially in future periods.

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 licensing agreements related to the Cell-in-a-Box® technology for $1,549,427 and diabetes license for $2,000,000 for an aggregatetotal 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 three months ended July 31, 2022, and 2021.

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 was identified or recorded during the three months ended July 31, 2022, and 2021.

Fair Value of Financial Instruments

For certain of the Company's non-derivative financial instruments, including cash, accounts payable and accrued expenses, the carrying amount approximates fair value due to the short-term maturities of these instruments.

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 consolidated balance sheets for current 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. 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.

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 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.

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security ("CARES") Act to provide certain relief as a result of the Coronavirus Disease 2019 outbreak. The Company maintains a full valuation allowance on its U.S. net deferred tax assets. Deferred tax asset remeasurement (tax expense) was offset by a net decrease in valuation allowance, which resulted in no impact on the Company's income tax expense. Therefore, the Company does not expect the provisions in the CARES Act will impact the Company's Condensed Consolidated Financial Statements.

On March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, the Company does not expect the provisions of this Act will impact the Company's Condensed Consolidated Financial Statements.

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 July 31, 2022, and 2021 were $159,273 and $143,613, 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 $1,760,000 and $679,000 at July 31, 2022 and 2021, respectively. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash.

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.

Recent Accounting Pronouncements

In March 2020, the FASB issued ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting ("ASU 2020-04") and also issued subsequent amendments to the initial guidance (collectively, "Topic 848"). Topic 848 is effective for all entities as of March 12, 2020, through December 31, 2022, and provides optional guidance for contract modifications and certain hedging relationships associated with the transition from reference rates that are expected to be discontinued. The Company will adopt Topic 848 when relevant contracts are modified upon transition to alternative reference rates. The Company does not expect the adoption of Topic 848 to have a material impact on the Company's Condensed Consolidated Financial Statements.

NOTE 3 – ACCRUED EXPENSES

Accrued expenses at July 31, 2022, and April 30, 2022, are summarized below:

	July 31, 2022	April 30, 2022
Payroll related costs	$ 148,581	$ 118,062
R&D costs	377,155	377,155
Other	4,595	3,792
Total	$ 530,331	$ 499,009

The Director and Officer Insurance Policy for the policy term of September 8, 2021, through September 8, 2022, was paid in full on August 8, 2021. The Company financed the Director and Officer Insurance Policy for the policy term of March 8, 2021, through September 8, 2021. The financing agreement had an interest rate of 4.85% per annum and required eight monthly payments of $12,829. The unpaid balances as of July 31, 2022, and 2021, of $0 and $12,786, respectively, are included in accrued expenses.

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 months ended July 31, 2022, and 2021 is as follows:

During the three months ended July 31, 2020, three non-employee members of the Board were issued 1,000 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 $3,371 for the three months ended July 31, 2022, and 2021, respectively. There were zero unvested shares remaining related to such DLAs as of July 31, 2022.

In September 2020, a consultant was issued 333 shares of common stock in respect of his services as the Chairman of the Company's Medical and Scientific Advisory Board with vesting subject to the consultant continuing to provide services to the Company. The Company recorded a non-cash consulting expense in the amount of $0 and $2,125 for the three months ended July 31, 2022, and 2021, respectively. There were zero unvested shares remaining related to his compensation arrangement as of July 31, 2022, and 2021, respectively.

In January 2021, the Company awarded 4,400 shares of common stock to the executive officers of the Company as part of their compensation agreements for 2021. These shares vest monthly over a twelve-month period and are subject to the executive officers continuing to provide service under their compensation agreements. During the three months ended July 31, 2022, and 2021, the Company recorded a non-cash compensation expense in the amount of $0 and $11,055, respectively. There were zero and 1,833 unvested shares as of July 31, 2022, and 2021, respectively.

During the three months ended July 31, 2021, three non-employee members of the Board were issued 1,002 shares of common stock pursuant to their 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 $4,885 for the three months ended July 31, 2022, and 2021, respectively. There were zero unvested shares remaining related to such DLAs as of July 31, 2022, and 2021, respectively.

During the three months ended July 31, 2021, two consultants were issued 334 shares of common stock pursuant to their consulting agreements with the Company. The shares vest monthly over a twelve-month period and are subject to the consultants continuing to provide services under their consulting agreements. The Company recorded a non-cash consulting expense in the amount of $0 and $1,620 for the three months ended July 31, 2022, and 2021, respectively. There were zero and 251 unvested shares remaining related to these consulting agreements as of July 31, 2022, and 2021, respectively.

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. These shares vest monthly over a twelve-month period and are subject to the executive officers continuing to provide service under their compensation agreements. During the three months ended July 31, 2022, and 2021, the Company recorded a non-cash compensation expense in the amount of $2,750 and $0, respectively. There were 1,833 and zero unvested shares as of July 31, 2022, and 2021, respectively.

During the three months ended July 31, 2022, three non-employee members of the Board were issued 1,002 shares of common stock pursuant to their DLAs in respect of their service during that year. The shares were fully vested upon issuance. The Company recorded a non-cash expense of $2,278 and $0 for the three months ended July 31, 2022, and 2021, respectively. There were zero unvested shares remaining related to such DLAs as of July 31, 2022, and 2021, 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.

On April 9, 2021, the Third S-3 ("Third S-3") was declared effective by the Commission for a public offering of up to $100 million on a "shelf offering" basis. During August 2021, the Company sold and issued approximately 19.1 million shares of common stock, at prices ranging from $4.25 to $5.00 per share. Net of underwriting discounts, legal, accounting, and other offering expenses, the Company received approximately $87.4 million from the sale of these shares and the exercise of approximately 2.5 million warrant shares.

On August 9, 2021, the Company entered into an underwriting agreement to offer and sell shares of common stock, pre-funded warrants to purchase common stock and warrants to purchase common stock in a public offering ("First Offering"). The gross proceeds of the First Offering were $15 million, before deduction of underwriting discounts, commissions, and estimated offering expenses.

In August 2021, the Company received twenty-seven (27) cash exercise notices relating to the common warrants with respect to the First Offering totaling 2,522,387 warrant shares ("Warrant Exercises"). The Company received approximately $10,720,000 and issued 2,522,387 shares of common stock as a result of the exercise notices.

On August 19, 2021, the Company entered into a securities purchase agreement ("Securities Purchase Agreement") with certain institutional investors ("Purchasers") pursuant to which the Company agreed to sell in a registered direct offering ("Registered Direct Offering"), shares of the Company's common stock and pre-funded warrants to purchase shares of common stock. Further, pursuant to the Securities Purchase Agreement, in a concurrent private placement (together with the Registered Direct Offering, "Second Offering"), the Company also agreed to issue to the Purchasers unregistered warrants ("Series A Warrants") to purchase shares of common stock. The Company received gross proceeds from the Second Offering, before deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $70 million. On November 17, 2021, the Company's Registration Statement on Form S-3 registering the resale of the common stock underlying the Series A Warrants was declared effective by the U.S. Securities and Exchange Commission ("Commission").

A summary of the Company's non-vested restricted stock activity and related weighted average grant date fair value information for the last three months ended July 31, 2022, are as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested, at April 30, 2022	2,933	2.50
Granted	1,002	2.46
Vested	(2,102)	2.06
Expired	–	–
Unvested, at July 31, 2022	1,833	$ 2.50

NOTE 5 – STOCK OPTIONS AND WARRANTS

2021 Equity Incentive Plan

Effective June 30, 2021, the Company implemented the 2021 Equity Incentive Plan ("2021 Equity Plan") as approved by the Company's stockholders. The 2021 Equity Plan is administered by the Compensation Committee of the Board and has 166,667 shares available under this plan. The 2021 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 2021 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 July 31, 2022, the Company had 38,269 outstanding stock options to its directors and officers (collectively, "Employee Options") and consultants ("Non-Employee Options").

During the three months ended July 31, 2022, and 2021, the Company granted 1,002 and 1,000 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:

	Three Months Ended July 31,	
	2022	2021
Risk-free interest rate	2.9%	0.87%
Expected volatility	139%	113%
Expected lives (years)	2.5	2.5
Expected dividend yield	0.00%	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 three months ended July 31, 2022, and 2021, the Company used a calculated volatility for each grant. 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.

During the three months ended July 31, 2022, the Company granted no Non-Employee Options.

A summary of the Company's stock option activity and related information for the three months ended July 31, 2022 are shown below:

Options	**Weighted Average Exercise Price per Share**	**Weighted Average Grant Date Fair Value per Share**
Outstanding, April 30, 2022	40,900	$ 53.05
Issued	1,002	2.27
Forfeited	(3,633)	104.62
Outstanding, July 31, 2022	38,269	$ 46.83
Exercisable, July 31, 2022	35,769	$ 49.92
Vested and expected to vest	38,269	$ 46.83

A summary of the activity for unvested stock options during the three months ended July 31, 2022, is as follows:

	Options	Weighted Average Grant Date Fair Value per Share
Unvested, April 30, 2022	4,000	$ –
Issued	1,002	2.27
Vested	(2,502)	–
Forfeited	–	–
Unvested, July 31, 2022	2,500	$ 2.50

The Company recorded $4,595 and $24,144 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 July 31, 2022, and 2021, respectively. At July 31, 2022, there remained $4,859 of unrecognized compensation expense related to unvested Employee Options granted to officers and directors, to be recognized as expense over a weighted-average period of the remaining eight months in the calendar year. The unvested options vest at 500 shares per month and are expected to be fully vested on December 31, 2022.

The following table summarizes the outstanding stock options by exercise price at July 31, 2022:

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
$ 82.95	333	0.10	$ 82.95	333	$ 82.95
$ 83.70	6,000	0.25	$ 83.70	6,000	$ 83.70
$ 80.10	800	1.10	$ 80.10	800	$ 80.10
$ 80.85	667	0.38	$ 80.85	667	$ 80.85
$ 102.45	333	0.46	$ 102.45	333	$ 102.45
$ 97.35	333	0.60	$ 97.35	333	$ 97.35
$ 74.25	6,000	0.98	$ 74.25	6,000	$ 74.25
$ 57.00	800	2.15	$ 57.00	800	$ 57.00
$ 60.60	667	0.88	$ 60.60	667	$ 60.60
$ 55.50	333	0.95	$ 55.50	333	$ 55.50
$ 51.00	333	1.10	$ 51.00	333	$ 51.00
$ 61.20	6,000	1.46	$ 61.20	6,000	$ 61.20
$ 36.00	667	1.38	$ 36.00	667	$ 36.00
$ 37.05	333	1.46	$ 37.05	333	$ 37.05
$ 15.75	333	1.60	$ 15.70	333	$ 15.70
$ 10.05	6,000	2.05	$ 10.05	6,000	$ 10.05
$ 26.55	667	1.88	$ 26.55	667	$ 26.55
$ 16.20	334	1.96	$ 16.20	334	$ 16.20
$ 3.19	334	2.10	$ 3.19	334	$ 3.19
$ 2.50	6,000	2.65	$ 2.50	3,500	$ 2.50
$ 2.29	668	2.38	$ 2.29	668	$ 2.29
$ 2.24	334	2.46	$ 2.24	334	$ 2.24
Total	38,269	1.19	$ 46.83	35,769	$ 46.83

The aggregate intrinsic value of outstanding options as of July 31, 2022, was $117. This represents options whose exercise price was less than the closing fair market value of the Company’s common stock on July 31, 2022, of approximately $2.39 per share.

Warrants

The warrants issued by the Company are equity classified. The fair value of the warrants was recorded as additional paid-in-capital, and no further adjustments are made.

The Company concluded the following warrants met the permanent equity criteria classification as they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued. The warrants are immediately exercisable and do not embody an obligation for the Company to repurchase the shares. The warrants also permit the holders to receive a fixed number of shares upon exercise and do not provide any guarantee of value or return.

The Company elected to early adopt ASU No. 2020-06 Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) as of May 1, 2021. The early adoption of ASU No.2020-06 had an immaterial effect on the Company's consolidated financial statements.

Effective August 12, 2021, the Company issued Common Stock Warrant Agreements ("Common Warrants") with respect to the First Offering. The Company issued Common Warrants to purchase 4,028,528 shares of common stock based upon the underwriting agreement with H.C. Wainwright & Co., LLC ("Wainwright"). The Common Warrants have a term of five years with an exercise price of $4.25 per warrant share, are fully vested upon issuance and have a cashless exercise feature. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate fair value of these Common Warrants to be approximately $9,385,000 and is included in the non-cash equity issuance costs as presented on the Consolidated Statements of Cash Flows of $34,477,000.

Additionally, with respect to the First Offering, the Company issued common stock warrant agreements to Wainwright ("Underwriter Warrants") to purchase 264,706 shares of common stock. The Underwriter Warrants have a term of five years with an exercise price of $5.3125 per warrant share, are fully vested upon issuance and have a cashless exercise feature. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate fair value of these Underwriter Warrants to be approximately $601,000 and is included in the non-cash equity issuance costs as presented on the Consolidated Statements of Cash Flows of $34,477,000.

Effective August 12, 2021, the Company issued 899,027 pre-funded warrants ("Pre-funded Warrants") to purchase common stock and Common Warrants based upon the underwriting agreement with Wainwright with respect to the First Offering. The Pre-funded Warrants required a payment upon issuance of $4.249 per warrant share and are fully vested upon issuance. The Company received approximately $3,820,000 from the issuance of the Pre-funded Warrants. The Pre-funded Warrants have an exercise price of $0.001 per share, are exercisable immediately, have a cashless exercise feature and do not have an expiration date. In August 2021, all 899,027 of the Pre-funded Warrants issued under the underwriting agreement were exercised. The Company received $899 as a result of the exercise of the Pre-funded Warrants and issued 899,027 shares of common stock as a result of the exercise notices. There was no additional effect on the Pre-funded Warrants as they were fully exercised.

Effective August 23, 2021, the Company issued additional Common Stock Warrant Agreements ("Series A Warrants") with respect to the Second Offering. The Company issued Series A Warrants to purchase 7,000,000 shares of common stock based upon the Securities Purchase Agreement with certain institutional investors. The Series A Warrants have a term of five years with an exercise price of $5.00 per warrant share, are fully vested upon issuance, have a cashless exercise feature and are exercisable immediately. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate fair value of these Series A Warrants to be approximately $21,340,000 and is included in the non-cash equity issuance costs as presented on the Consolidated Statements of Cash Flows of $34,477,000.

Effective August 23, 2021, the Company issued additional Common Stock Warrant Agreements ("Placement Agent Warrants") with respect to the Second Offering. The Company issued Placement Agent Warrants to purchase 1,050,000 shares of common stock to Wainwright or its designees based upon Wainwright acting as placement agent. The Placement Agent Warrants have a term of five years with an exercise price of $6.25 per warrant share, are fully vested upon issuance, have a cashless exercise feature and are exercisable immediately. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate fair value of these Placement Agent Warrants to be approximately $3,151,000 and is included in the non-cash equity issuance costs as presented on the Consolidated Statements of Cash Flows of $34,477,000.

Effective August 23, 2021, the Company issued Pre-funded Warrants pursuant to the Second Offering to purchase 5,570,000 shares of common stock in the amount of approximately $27,844,000 which required payments upon issuance of $4.999 per warrant share. The Pre-funded Warrants have an exercise price of $0.001 per share, are fully vested upon issuance, are immediately exercisable, have a cashless exercise feature and do not have an expiration date. As of July 31, 2022, 5,500,000 of the Pre-funded Warrants have been exercised for aggregate gross proceeds of $5,500, which resulted in the issuance of 5,500,000 shares. As of July 31, 2022, the remaining unexercised Pre-funded Warrants were 70,000 shares that can be exercised for $70. The Company received a total of $4,749,930 pursuant to the issuance of the Pre-funded Warrants and these shares remain unissued as of July 31,2022.

In August 2021, the Company received twenty-seven cash exercise notices relating to the Common Warrants with respect to the First Offering totaling 2,522,387 warrant shares. The Company received approximately $10,720,000 and issued 2,522,387 shares of common stock as a result of the exercise notices.

Series A Warrants and Placement Agent Warrants were issued pursuant to the Securities Purchase Agreement dated as of August 19, 2021. At the time, the Series A Warrants and the Placement Agent Warrants were issued, neither the Series A Warrants, the Placement Agent Warrants nor the underlying common stock was registered pursuant to the Securities Act. The Company registered the common stock underlying the Series A Warrants and the Placement Agent Warrants pursuant to a Registration Statement on Form S-3 ("Registration Statement") filed with the Commission on November 8, 2021. The Registration Statement became effective on November 17, 2021.

A summary of the Company's warrant activity and related information for the three months ended July 31, 2022, are shown below:

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, April 30, 2022	10,772,736	$ 4.59
Issued	-	–
Exercised	(880,000)	–
Expired	(1,889)	–
Outstanding, July 31, 2022	9,890,847	–
Exercisable, July 31, 2022	9,890,847	$ 4.99

The following table summarizes additional information concerning warrants outstanding and exercisable at July 31, 2022:

Exercise Prices	Number of Warrant Shares Exercisable at July 31, 2022	Weighted Average Remaining Contractual Life Years	Weighted Average Exercise Price Per Share
$4.25	1,506,141	4.03	
$5.3125	264,706	4.03	
$5.00	7,000,000	4.07	
$6.25	1,050,000	4.05	
$0.001	70,000	–	
	9,890,847	4.06	$ 4.99

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 – OTHER RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the three months ended July 31, 2022, and 2021, 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 $60,000 and $58,000 in the three months ended July 31, 2022, and 2021, 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, 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. The agreement has been automatically renewed annually. The amounts incurred for the three months ended July 31, 2022, and 2021, were approximately $45,000 and $32,000, respectively.

The Company's Director of Administration who has been serving in that capacity for seven years is the wife of the Company's Chief Executive Officer.

One of the Company's directors is party to a short put option, which requires him to purchase, at the election of the option counterparty, 795,000 shares of the Company's common stock at a price of $2.50 per share. The short put option expires on October 21, 2022.

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 May 2019, the Company entered into a lease for its office space in Laguna Hills, California for a one-year lease for the leased premises. The term of the lease expired on August 31, 2020.

On May 28, 2020, the Company entered into an additional six-month lease of this office space, commencing on September 1, 2020. The term of the new lease expired on February 28, 2021.

On May 24, 2021, the Company entered into an additional six-month lease of this office space, commencing on September 1, 2021, which expired on February 28, 2022.

In October 2021, the Company moved the Company's headquarter from Laguna Hills, California to Las Vegas. Nevada. In doing so, the Company entered into a lease for office space in Las Vegas, Nevada. The term of the lease expired on April 30, 2022.

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

Rent expenses for the office for the three months ended July 31, 2022, and 2021, were $1,100 and $3,738, respectively.

The following table summarizes the Company's aggregate future minimum lease payments required under the operating lease as of:

Year Ending April 30,	Amount
2023	$ 3,342
	$ 3,342

Compensation Agreements

The Company entered into executive compensation agreements with its three executive officers in March 2015, each of which was amended in December 2015 and March 2017. Each agreement has a term of two years with annual extensions thereafter unless the Company or the officer provides written notification of termination at least ninety days prior to the end of the term or subsequent extensions. The Company also entered a compensation agreement with a Board member in April 2015 which continued in effect until amended in May 2017.

The Company entered into amended and restated executive compensation agreements with two executive officers with an effective date of January 1, 2022 ("Amendment Date"). Each agreement has a term of three years from the Amendment Date ("Initial Term") and has automatic renewals of one year ("Renewal Term") unless the Company or the officer provides written notice of termination at least ninety days prior to the end of the Initial Term or the Renewal Term.

In May 2017, the Company amended the compensation agreement with the Board members and the terms continue in effect until a member is no longer on the Board.

The Company had four independent directors. Each director receives the same compensation: (i) $12,500 in cash for each calendar quarter of service on the Board; (ii) 334 fully paid, non-assessable shares of the Company's restricted common stock ("Shares") annually; and (iii) a five-year option to purchase 334 Shares annually at an exercise price equal to the fair market value of the Shares on the date of grant. The Shares and the option Shares fully vest on the date of the grants. See Note 13 – Subsequent Events for a discussion of the Reconstituted Board.

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 $373,000, of which the related party (SG Austria and its subsidiaries) portion will be approximately $291,000. 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 July 31, 2022, the Company had federal and state net operating loss carryforwards of approximately $53,885,000 and $50,122,000, respectively, available to offset against future taxable income; these operating loss carryforwards expire in 2021 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 three months ended July 31, 2022, the Company had an ownership change in August 2021. As a result in the change in-control that occurred in the Company's shareholder base in August 2021, approximately $37,083,000 and $40,838,000 federal and state net operating loss carryforwards, respectively, became limited in their availability. The remaining net operating loss carryforwards are approximately $16,802,000 and $9,284,000 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 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 three months ended July 31, 2022, and 2021, the Company had accrued no interest or penalties related to uncertain tax positions.

See Note 10 of Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended April 30, 2022, for additional information regarding income taxes.

NOTE 10 – EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing earnings 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 stock options and warrants. During the three months ended July 31, 2022, and 2021, the Company incurred losses. 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 July 31,	
	2022	**2021**
Net loss	$ (1,545,012)	$ (1,025,418)
Basic weighted average number of shares outstanding	20,829,315	1,591,306
Diluted weighted average number of shares outstanding	20,829,315	1,591,306
Basic loss per share	$ (0.07)	$ (0.64)
Diluted loss per share	$ (0.07)	$ (0.64)

The table below sets forth these potentially dilutive securities:

	Three Months Ended July 31,	
	2022	**2021**
Excluded options	38,269	42,333
Excluded warrants	9,890,847	2,981
Total excluded options and warrants	9,929,116	45,314

NOTE 11 – PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, with a par value of $0.0001, of which one share has been designated as "Series A Preferred Stock". As of July 31, 2022, there are no shares of 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 Company's Board of Directors authorized a share repurchase program to acquire its outstanding Common Stock for up to $10,000,000. In conjunction with the share repurchase program, 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. In July 2022, the Company repurchased 851,981 shares at a total cost, including commissions, of $2,090,847. These shares are treated as Treasury Stock using the cost method. The 851,981 shares repurchased are included in Treasury Stock in the accompanying Condensed Consolidated Balance Sheets. At July 31, 2022, $7,909,153 remains available to repurchase the Company's Common Stock pursuant to the share repurchase program.

NOTE 13 – SUBSEQUENT EVENTS

On August 15, 2022, the Company entered into the Cooperation Agreement with Iroquois Master Fund Ltd. and its affiliates. Pursuant to the Cooperation Agreement, the Company and the Board of Directors of the Company ("Board") have: (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. Following such resignations and appointments, the Board, as reconstituted, consists of the following seven members: Kenneth L. Waggoner (Chairman), Jonathan L. Schechter, Joshua N. Silverman, Daniel Allen, Daniel S. Farb, Jack E. Stover and Dr. Michael M. Abecassis ("Reconstituted Board").

The Reconstituted 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 Board. The Business Review Committee is 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. During this time, 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.

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 SEC, including our Annual Report on Form 10-K, for the fiscal year ended April 30, 2022 and the following factors and risks:

- our expectations of future revenues, expenditures, capital or other funding requirements;
- 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;

- 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; and

- 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.

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:

- 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 products 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, 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. See Note 13 – Subsequent Events to the Notes to Condensed Consolidated Financial Statements. 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 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, 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 Business Review Committee completes its evaluation of the Company's programs and the Company enters into a new framework for its relationship with SG Austria, spending on the Company's 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, 8 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 the Company's curtailment of spending pending review of the Company's programs by the Business Review Committee and the Reconstituted Board (See "Business Review Committee"), including seeking a new framework for its relationship with SG Austria and its subsidiaries.

Reverse Stock Split

Effective July 12, 2021, we filed a Certificate of Change with the Nevada Secretary of State that authorized a 1:1500 reverse stock split of our common stock. The reverse stock split resulted in reducing the authorized number of shares of our common stock from 50 billion to thirty-three million three hundred thirty-three thousand three hundred thirty-four with a par value of $0.0001 per share. Any fractional shares resulting from the reverse stock split were rounded up to the next whole share. All warrants, option, share and per share information in this Report gives retroactive effect to such 1:1500 reverse stock split.

Impact of COVID-19 on Our Financial Condition and Results of Operations

The coronavirus SARS Cov2 ("COVID-19") pandemic continues to cause uncertainty and significant, industry-wide delays in clinical trials. The availability of vaccines holds promise for the future; however, new variants of the virus and potential waning immunity from vaccines may result in continued impact from COVID-19 in the future, which could adversely impact our operations. Although we are not yet in a clinical trial, we have filed an IND with the FDA to commence a clinical trial in LAPC. While the IND has been placed on clinical hold by the FDA, we have assessed the impact of COVID-19 on our operations.

Many clinical trials have been delayed due to COVID-19. There are numerous reasons for these delays. For example, patients have shown a reluctance to enroll or continue in a clinical trial due to fear of exposure to COVID-19 when they are in a hospital or doctor's office. There are local, regional and state-wide orders and regulations restricting usual normal activity by people. These discourage and interfere with patient visits to a doctor's office if the visit is not COVID-19 related. Healthcare providers and health systems have shifted their resources away from clinical trials toward the care of COVID-19 patients. The FDA and other healthcare providers are making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to COVID-19.

As a result of COVID-19 and the mitigation efforts to address it, we may experience additional disruptions that could adversely impact our business and clinical trial, if allowed to proceed, including: (i) delays or difficulties in enrolling patients in our clinical trial if the FDA allows us to go forward with the trial; (ii) delays or difficulties in clinical site activation, including difficulties in recruiting clinical site investigators and clinical site personnel; (iii) delays in clinical sites receiving the supplies and materials needed to conduct our clinical trial, including interruption in global shipping that may affect the transport of our clinical trial product; (iv) changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trial is to be conducted, which may result in unexpected costs, or to discontinue the clinical trial altogether; (v) diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trial; (vi) interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; (vii) risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; (viii) delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; (ix) limitations in employee resources that would otherwise be focused on the conduct of our clinical trial because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; (x) refusal of the FDA to accept data from clinical trials in affected geographies; and (xi) interruption or delays to our clinical trial activities.

As a result of COVID-19, commencement of our planned clinical trial to treat LAPC may be delayed beyond the lifting of the clinical hold by the FDA should that occur. Also, enrollment may be difficult for the reasons discussed above. In addition, after enrollment in the trial, if patients contract COVID-19 during their participation in the trial or are subject to isolation or shelter in place restrictions, this may cause them to drop out of our clinical trial, miss scheduled therapy appointments or follow-up visits or otherwise fail to follow the clinical trial protocol. If patients are unable to follow the clinical trial protocol or if the trial results are otherwise affected by the consequences of COVID-19 on patient participation or actions taken to mitigate COVID-19 spread, the integrity of data from the clinical trial may be compromised or not be accepted by the FDA. This could further adversely impact or delay our clinical development program if the FDA allows it to proceed.

Clinical trials in the biopharma industry may be delayed due to COVID-19. There are numerous reasons for these potential delays. The impact relates to delays in: (i) completing studies required by the FDA; (ii) manufacturing a new batch of CypCap™ for our planned clinical trial in LAPC; (iii) manufacturing syringes of CypCaps™ for some of the preclinical studies to be completed and use in our Malignant Ascites Program; and (iv) securing third party contractors to conduct various R&D projects. As a result, there may be delays in generating responses to the requests from the FDA related to the clinical hold. Many of these potential delays are also due to the impact of COVID-19 in foreign countries where we are conducting these preclinical studies, including India, Europe, Singapore and Thailand. There have also been supply chain interruptions due to COVID-19.

It is highly speculative in projecting the effects of COVID-19 on our proposed clinical development program and the Company generally. Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The continuation of COVID-19 could materially disrupt our business and operations, hamper our ability to raise additional funds or sell our securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations. The effects of COVID-19 quickly and dramatically change over time. Its evolution is difficult to predict, and no one is able to say with certainty when the pandemic will fully cease to have an impact on our operations.

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 tasked 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 months ended July 31, 2022 compared to three months ended July 31, 2021

Revenue

We had no revenues for the three months ended July 31, 2022, and 2021.

Operating Expenses

The total operating expenses during the three months ended July 31, 2022, increased by $657,257 to $1,680,608 from $1,023,351 in the three months ended July 31, 2021. The increase is mainly attributable to increases in R&D costs, compensation expense, legal and professional expense, and consulting expense in 2022 from 2021, net of a decrease in director fees.

Operating expenses:	Three Months Ended July 31, 2022	Change - Increase (Decrease) and Percent	Three Months Ended July 31, 2021
R&D	$ 159,273	$ 15,660	$ 143,613
		11%	
Compensation expense	$ 327,718	$ 58,833	$ 268,885
		22%	
Director fees	$ 52,727	$ (10,432)	$ 63,159
		(17%)	
General and administrative, legal and professional	$ 1,140,890	$ 593,196	$ 547,694
		108%	

Loss from Operations

Loss from operations during the three months ended July 31, 2022, increased by $657,257 to $1,680,608 from $1,023,351 in the three months ended July 31, 2021. The increase is mainly attributable to increases in R&D costs, compensation expense, legal and professional expense, and consulting expense in 2022 from 2021, net of a decrease in director fees. The increase is mainly attributable to contested proxy expenses incurred which were approximately $578,000 in legal expenses.

Other Income (Expenses), Net

Other income, net for the three months ended July 31, 2022, was $135,596 as compared to other expense, net of $2,067 in the three months ended July 31, 2021. Other income, net for the three months ended July 31, 2022, is attributable to interest income of $139,502 and other expenses of $3,906. Other income, net for the three months ended July 31, 2021, is attributable to interest expense of $467 and other expenses of $1,600.

Discussion of Operating, Investing and Financing Activities

The following table presents a summary of our sources and uses of cash for the three months ended July 31, 2022, and 2021.

	Three Months Ended July 31, 2022	Three Months Ended July 31, 2021
Net cash used in operating activities:	$ (1,084,378)	$ (1,241,221)
Net cash used in investing activities:	$ –	$ –
Net cash used by financing activities:	$ (2,089,967)	$ –
Effect of currency rate exchange	$ 1,304	$ (1,615)
Decrease in cash	$ 3,173,041	$ 1,242,836

Operating Activities:

The cash used in operating activities for the three months ended July 31, 2022, and 2021, is a result of our net losses offset by securities issued for services and compensation, changes to prepaid expenses, accounts payable and accrued expenses.

Investing Activities: We had no investing activities for the three months ended July 31, 2022, and 2021.

Financing Activities:

The cash used from financing activities for the three months ended July 31, 2022, is mainly attributable to the repurchase of common stock net of the proceeds from the sale of our common stock.

Liquidity and Capital Resources

As of July 31, 2022, our cash and cash equivalents totaled approximately $82.2 million, compared to approximately $959,000 as of July 31, 2021. Working capital was approximately $81.2 million as of July 31, 2022, and approximately $583,000 as of July 31, 2021. The increase in cash is attributable to proceeds from the sale of our common stock net of an increase in our operating expenses.

On August 9, 2021, the Company entered into an underwriting agreement to offer and sell shares of common stock, pre-funded warrants to purchase common stock and warrants to purchase common stock in a public offering (“First Offering”). The gross proceeds of the First Offering were $15 million, before deduction of underwriting discounts, commissions, and estimated offering expenses.

In August 2021, the Company received twenty-seven (27) cash exercise notices relating to the common warrants with respect to the First Offering totaling 2,522,387 warrant shares (“Warrant Exercises”). The Company received approximately $10,720,000 and issued 2,522,387 shares of common stock as a result of the exercise notices.

On August 19, 2021, the Company entered into a securities purchase agreement (“Securities Purchase Agreement”) with certain institutional investors (“Purchasers”) pursuant to which the Company agreed to sell in a registered direct offering (“Registered Direct Offering”), shares of the Company’s common stock and pre-funded warrants to purchase shares of common stock. Further, pursuant to the Securities Purchase Agreement, in a concurrent private placement (together with the Registered Direct Offering, “Second Offering”), the Company also agreed to issue to the Purchasers unregistered warrants (“Series A Warrants”) to purchase shares of common stock. The Company received gross proceeds from the Second Offering, before deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $70 million. On November 17, 2021, the Company’s Registration Statement on Form S-3 registering the resale of the common stock underlying the Series A Warrants was declared effective by the U.S. Securities and Exchange Commission (“Commission”).

In August 2021, funding in the amount of approximately $87.4 million was provided by investors to maintain and expand our operations and R&D through the First Offering and the Second Offering and the Warrant Exercises. Sales of our common stock, pre-funded warrants and exercise of Common Warrants occurred in the First Offering, Second Offering, and the Warrant Exercises.

On May 14, 2018, we entered into amendments to all of the material agreements with SG Austria and Austrianova (see Section entitled, History of the Business" in Item 1. Business in our Form 10-K for the period ended April 30, 2022, for a description of these amendments). These arrangements are under review by our Business Review Committee and Reconstituted Board which has curtailed spending on our programs until their review is complete and recommendations are made. This includes seeking a new framework for the Company's relationship with SG Austria and Austrianova. In the event the Company is unsuccessful in such efforts, 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. We have no other off-balance sheet arrangements that could have a material current effect or that are reasonably likely to have a material adverse effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Off-Balance Sheet Arrangements

Except as described below, we have no off-balance sheet arrangements that could have a material current effect or that are reasonably likely to have a material adverse effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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 $373,000, of which the related party portion will be approximately $291,000. 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 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.

Research and Development Expenses

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 R&D and that have no alternative future use are expensed when incurred. Technology developed for use in our product candidates is expensed as incurred until technological feasibility has been established.

Stock-Based Compensation

Our stock-based compensation plans are described in Notes 2 and 5 of the Notes to our Condensed Consolidated Financial Statements contained in this Report. We follow the provisions of ASC 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees.

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. Potentially dilutive stock options and warrants to purchase 9,929,116 and 45,314 post reverse stock split shares of common stock at July 31, 2022, and 2021, respectively, were excluded from the computation of diluted net income (loss) per share because the effect would be anti-dilutive.

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 Report.

Related Party Disclosures

In addition to the disclosures made in Note 7- Related Party Transactions and Note 8 of the Company's Notes to Condensed Consolidated Financial Statements with respect to SG Austria and Vin-de-Bona, the Company notes the following:

The Company's Director of Administration who has been serving in that capacity for eight years is the wife of the Company's Chief Executive Officer.

One of the Company's directors is party to a short put option, which requires him to purchase, at the election of the option counterparty, 795,000 shares of the Company's common stock at a price of $2.50 per share. The short put option expires on October 21, 2022.

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 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 Chief Executive Officer, President and General Counsel, 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 September 7, 2022, 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 SEC on July 28, 2022, 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 three months ended July 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

The Certifications of our Principal Executive and Principal 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 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 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 SEC on July 28, 2022. These risk factors could materially harm our business, operating results and financial condition. Additional factors and uncertainties not currently known to us or that we currently consider immaterial also may materially adversely affect our business, financial condition or future results.

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

During the three-months ended July 31, 2022, we issued an aggregate of 1,002 unregistered shares of common stock to three of our directors pursuant to their DLAs. The non-cash expense for these share issuances totaled $2,278.

During the three-months ended July 31, 2022, we issued an aggregate of 1,002 stock options to three of our directors pursuant to their DLAs. The non-cash expense for stock options totaled $1,677.

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

Issuer Purchases of Equity Securities

The table below summarizes information about the Company's purchases of its equity securities during the quarterly period ended July 31, 2022.

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
May 1, 2022 - May 31, 2022	–	$ –	–	$ 10,000,000
June 1, 2022 – June 30, 2022	–	$ –	–	$ 10,000,000
July 1, 2022 - July 31, 2022	851,981	$ 2.4341	851,981	$ 7,909,153
	851,981	$ 2.4341	851,981	$ 7,909,153

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
10.1	Cooperation Agreement dated August 15, 2022, by and between PharmaCyte Biotech, Inc. and Iroquois Master Fund Ltd. and its affiliates	Incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed on August 16, 2022
10.2 †	Form of Director Offer Letter	Incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed on August 16, 2022
31.1	Principal Executive Officer Certification required by Rules 13a-14 and 15d-14as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Principal Executive Officer Certification required by Rules 13a-14 and 15d-14as 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 Executive 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).	

† A contract, compensatory plan or arrangement to which a director or executive officer is a party or in which one or more directors or executive officers are eligible to participate.

SIGNATURES

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

PharmaCyte Biotech, Inc.

September 14, 2022

By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

September 14, 2022

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

EXHIBIT 31.1

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, Kenneth L. Waggoner, 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 July 31, 2022;

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: September 14, 2022

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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 July 31, 2022;

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: September 14, 2022

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

EXHIBIT 32.1

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 July 31, 2022 as filed with the United States Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Kenneth L. Waggoner, 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: September 14, 2022

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: 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.

EXHIBIT 32.2

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 July 31, 2022 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: September 14, 2022

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.