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

Form 10-Q

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **March 31, 2022**

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from _____ to _____

Commission file number **001-31392**

PLURISTEM THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

98-0351734

(IRS Employer
Identification No.)

MATAM Advanced Technology Park, Building No. 5, Haifa, Israel 3508409

(Address of principal executive offices)

011-972-74-7108600

(Registrant's telephone number)

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 Shares, par value \$0.00001	PSTI	Nasdaq Global 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 past 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 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

- | | | | |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | | |

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

State the number of shares outstanding of each of the issuer's classes of common shares as of the latest practicable date: 32,347,584 common shares issued and outstanding as of May 4, 2022.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of March 31, 2022

(Unaudited)

**PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

As of March 31, 2022

U.S. DOLLARS IN THOUSANDS

(Unaudited)

INDEX

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PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	Note	March 31, 2022	June 30, 2021
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 23,791	\$ 31,241
Short-term bank deposits		38,189	33,709
Restricted cash		470	597
Prepaid expenses and other current assets		1,863	1,824
<u>Total current assets</u>		64,313	67,371
LONG-TERM ASSETS:			
Long-term deposits		4,235	23,269
Restricted bank deposits		669	-
Severance pay fund		753	664
Property and equipment, net		787	1,499
Operating lease right-of-use asset	3g	8,353	728
Other long-term assets		17	7
<u>Total long-term assets</u>		14,814	26,167
<u>Total assets</u>		\$ 79,127	\$ 93,538

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Note</u>	<u>March 31, 2022</u>	<u>June 30, 2021</u>
LIABILITIES AND EQUITY			
CURRENT LIABILITIES			
Trade payables		\$ 2,394	\$ 2,526
Accrued expenses		2,085	5,941
Operating lease liability		669	634
Accrued vacation and recuperation		1,126	1,203
Other accounts payable		1,548	1,213
<u>Total</u> current liabilities		<u>7,822</u>	<u>11,517</u>
LONG-TERM LIABILITIES			
Accrued severance pay		967	920
Operating lease liability	3g	7,271	100
Loan from the European Investment Bank (“EIB”)	4	22,924	23,850
<u>Total</u> long-term liabilities		<u>31,162</u>	<u>24,870</u>
COMMITMENTS AND CONTINGENCIES	3		
EQUITY			
Share capital:	5		
Common shares, \$0.00001 par value per share:			
Authorized: 60,000,000 shares			
Issued and outstanding: 32,342,396 shares as of March 31, 2022, 31,957,782 shares as of June 30, 2021		*	*
Additional paid-in capital		400,351	387,172
Accumulated deficit		(362,258)	(330,021)
<u>Total</u> shareholders’ equity		<u>38,093</u>	<u>57,151</u>
Non-controlling interests		2,050	-
Total equity		<u>40,143</u>	<u>57,151</u>
<u>Total</u> liabilities and equity		<u>\$ 79,127</u>	<u>\$ 93,538</u>

(*) Less than \$1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Nine months ended</u> <u>March 31</u>		<u>Three months ended</u> <u>March 31,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenues	\$ 234	\$ -	\$ 234	\$ -
Operating expenses:				
Research and development expenses	\$ (19,205)	\$ (22,026)	\$ (6,273)	\$ (7,824)
Less: participation by the Israeli Innovation Authority (IIA), Horizon 2020 and other parties	189	445	117	158
Research and development expenses, net	(19,016)	(21,581)	(6,156)	(7,666)
General and administrative expenses	(13,929)	(14,455)	(4,553)	(6,559)
Operating loss	(32,711)	(36,036)	(10,475)	(14,225)
Financial income	1,097	912	678	125
Financial expenses	(676)	(173)	(121)	(154)
Financial income (expenses), net	421	739	557	(29)
Net loss	<u>\$ (32,290)</u>	<u>\$ (35,297)</u>	<u>\$ (9,918)</u>	<u>\$ (14,254)</u>
Net loss attributed to non-controlling interest	(53)	-	(53)	-
Net loss attributed to shareholders	<u>(32,237)</u>	<u>(35,297)</u>	<u>(9,865)</u>	<u>(14,254)</u>
Loss per share:				
Basic and diluted net loss per share	<u>\$ (1.00)</u>	<u>\$ (1.31)</u>	<u>\$ (0.31)</u>	<u>\$ (0.48)</u>
Weighted average number of shares used in computing basic and diluted net loss per share	<u>32,131,503</u>	<u>26,936,831</u>	<u>32,261,628</u>	<u>29,617,233</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Common Shares</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Shareholders'</u>
			<u>Capital</u>		<u>Equity</u>
Balance as of July 1, 2020	25,492,713	\$ (*)	\$ 336,257	\$ (280,156)	\$ 56,101
Share-based compensation to employees, directors and non-employee consultants	373,495	(*)	10,382	-	10,382
Issuance of common shares under the Open Market Sale Agreement, net of issuance costs of \$377	1,045,097	(*)	8,509	-	8,509
Exercise of warrants	51,999	(*)	364	-	364
Exercise of options by non-employee consultants	15,035	(*)	-	-	-
Issuance of common shares related to February 2021 registered direct offering net of issuance costs of \$1,923	4,761,905	(*)	28,077	-	28,077
Net loss	-	-	-	(35,297)	(35,297)
Balance as of March 31, 2021	<u>31,740,244</u>	<u>\$ (*)</u>	<u>\$ 383,589</u>	<u>\$ (315,453)</u>	<u>\$ 68,136</u>

(*) Less than \$1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Common Share</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Shareholders'</u>
			<u>Capital</u>		<u>Equity</u>
Balance as of January 1, 2021	25,839,286	\$ (*)	\$ 342,347	\$ (301,199)	\$ 41,148
Share-based compensation to employees, directors and non-employee consultants	210,977	(*)	5,525	-	5,525
Issuance of common Share under the Open Market Sale Agreement, net of issuance costs of \$151	928,076	(*)	7,640	-	7,640
Issuance of common shares related to February 2021 registered direct offering net of issuance costs of \$1,923	4,761,905	(*)	28,077	-	28,077
Net loss	-	-	-	(14,254)	(14,254)
Balance as of March 31, 2021	<u>31,740,244</u>	<u>\$ (*)</u>	<u>\$ 383,589</u>	<u>\$ (315,453)</u>	<u>\$ 68,136</u>

(*) Less than \$1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Shareholders' Equity</u>						
	<u>Common Shares</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>	<u>Non-</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Capital</u>	<u>Deficit</u>	<u>Shareholders'</u>	<u>controlling</u>	<u>Equity</u>
Balance as of July 1, 2021	31,957,782	\$ (*)	\$ 387,172	\$ (330,021)	\$ 57,151	\$ -	\$ 57,151
Share-based compensation to employees, directors, and non-employee consultants	384,614	(*)	7,522	-	7,522	260	7,782
Establishment of Plurinuva and Non-controlling interest in Plurinuva.	-	-	5,657	-	5,657	1,843	7,500
Net loss	-	-	-	(32,237)	(32,237)	(53)	(32,290)
Balance as of March 31, 2022	<u>32,342,396</u>	<u>\$ (*)</u>	<u>\$ 400,351</u>	<u>\$ (362,258)</u>	<u>\$ 38,093</u>	<u>\$ 2,050</u>	<u>\$ 40,143</u>

(*) Less than \$1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

U.S. Dollars in thousands (except share and per share data)

	<u>Shareholders' Equity</u>						<u>Non- controlling Interests</u>	<u>Total Equity</u>
	<u>Common Shares</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>			
	<u>Shares</u>	<u>Amount</u>						
Balance as of January 1, 2022	32,225,102	\$ (*)	\$ 392,233	\$ (352,393)	\$ 39,840	\$ -	\$39,840	
Share-based compensation to employees, directors, and non-employee consultants	117,294	(*)	2,461	-	2,461	260	2,721	
Establishment of Plurinuva and Non-controlling interest in Plurinuva	-	-	5,657	-	5,657	1,843	7,500	
Net loss	-	-	-	(9,865)	(9,865)	(53)	(9,918)	
Balance as of March 31, 2022	<u>32,342,396</u>	<u>\$ (*)</u>	<u>\$ 400,351</u>	<u>\$ (362,258)</u>	<u>\$ 38,093</u>	<u>\$ 2,050</u>	<u>\$40,143</u>	

(*) Less than \$1

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Nine months ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (32,290)	\$ (35,297)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	915	1,034
Share-based compensation to employees, directors and non-employee consultants	7,782	10,382
Decrease (increase) in prepaid expenses and other current assets and other long-term assets	(49)	261
Increase (decrease) in trade payables	(254)	146
Increase (decrease) in other accounts payable, accrued expenses, accrued vacation and recuperation and other current liabilities	(3,598)	1,940
Decrease in operating lease right-of-use asset and liability, net	(419)	(236)
Increase in interest receivable on short-term deposits	(247)	(219)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,072	666
Linkage differences and interest on long-term deposits and restricted bank deposits	(18)	-
Long term interest payable and foreign exchange differences on the EIB loan	(926)	-
Accrued severance pay, net	(42)	10
Net cash used for operating activities	\$ (28,074)	\$ (21,313)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	\$ (81)	\$ (331)
Proceeds from withdrawal of (investment in) short-term deposits	(4,233)	1,962
Proceeds from withdrawal of (investment in) long-term deposits	19,052	(13,688)
Net cash provided by (used by) investing activities	\$ 14,738	\$ (12,057)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Nine months ended March 31,	
	2022	2021
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds related to issuance of common shares, net of issuance costs	-	\$ 36,628
Proceeds related to exercise of warrants	-	364
Proceeds related to investment in subsidiary by non- controlling interest	7,500	-
Net cash provided by financing activities	<u>\$ 7,500</u>	<u>\$ 36,992</u>
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS	<u>(1,072)</u>	<u>-</u>
Increase (Decrease) in cash, cash equivalents and restricted cash	(6,908)	3,622
Cash, cash equivalents and restricted cash at the beginning of the period	31,838	9,229
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 24,930</u>	<u>\$ 12,851</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 1:-GENERAL

- a. Pluristem Therapeutics Inc., a Nevada corporation (“Pluristem Therapeutics” or “the Company”), was incorporated on May 11, 2001. Pluristem Therapeutics has a wholly owned subsidiary, Pluristem Ltd. (the “Subsidiary”), which is incorporated under the laws of the State of Israel. In January 2020, the Subsidiary established a wholly owned subsidiary, Pluristem GmbH (the “German Subsidiary”) which is incorporated under the laws of Germany. In January 2022, the Subsidiary established a subsidiary, Plurinuva Ltd. (“Plurinuva”) which is incorporated under the laws of Israel, which followed the execution of the collaboration agreement with Tnuva Food Industries – Agricultural Cooperative in Israel Ltd., through its fully owned subsidiary, Tnuva Food-Tech Incubator (2019), Limited Partnership (“Tnuva”). Pluristem Therapeutics, the Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Company” or “Pluristem.” The Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Subsidiaries.”

Pluristem Therapeutics’ common shares are traded on the Nasdaq Global Market and on the Tel-Aviv Stock Exchange under the symbol “PSTI”.

- b. The Company is a bio-technology company with an advanced cell-based technology platform, which operates in one business segment. The Company developed a unique three-dimensional, or 3D, technology platform for cell expansion with an industrial scale in-house Good Manufacturing Practice cell manufacturing facility. Pluristem uses its technology in the field of regenerative medicine and plans to utilize it in other industries and verticals that have a need for its mass scale and cost-effective cell expansion platform. Pluristem is focused on the research, development and manufacturing of cells, conducting clinical studies and the business development of cell therapeutics and cell based technologies

The Company has incurred an accumulated deficit of approximately \$362,258 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of March 31, 2022, the Company’s total shareholders’ equity amounted to \$38,093. During the nine-month period ended March 31, 2022, the Company incurred losses attributed to shareholders of \$32,237 and its negative cash flow from operating activities was \$28,074.

As of March 31, 2022, the Company’s consolidated cash position (cash and cash equivalents, short-term bank deposits and long-term bank deposits) totaled approximately \$66,215. The Company plans to continue to finance its operations from its current resources and by entering into licensing or other commercial agreements or establishment of joint ventures, from grants to support its research and development activities, and from sales of its equity securities. Management believes that its current resources, together with its existing operating plan, are sufficient for the Company to meet its obligations as they come due at least for a period of twelve months from the date of the issuance of these interim condensed consolidated financial statements. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of its product candidates.

- c. On January 5, 2022, the Subsidiary entered into definitive agreements (the “Agreements”) with Tnuva. Under the Agreements, the parties established a new company, Plurinuva, with the purpose of developing cultured meat products of all types and kinds. Plurinuva received exclusive, global, royalty bearing licensing rights to use Pluristem’s proprietary technology, intellectual property and knowhow in the field of cultured meat. Tnuva invested \$7,500 in Plurinuva and received 187,500 ordinary shares, representing 15.79% of the Plurinuva share capital as of February 24, 2022 (the “Closing Date”) and warrants (comprised of a “First Warrant” and “Second Warrant”) to invest up to an additional \$7,500 over a period of twelve months following the Closing Date.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 1:-GENERAL (CONT.)

The First Warrant issued to Tnuva permits Tnuva to purchase up to 125,000 ordinary shares of Plurinuva at an exercise price of \$40.00 per share, and has a term commencing on the Closing Date and ending at the earlier of (i) six months from the Closing Date, (ii) immediately prior to and subject to the consummation of an initial public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor. In addition, on the six months anniversary of the Closing Date, and provided that the First Warrant has not expired, Plurinuva shall issue to Tnuva the Second Warrant, which will permit Tnuva to purchase up to a number of ordinary shares of Plurinuva, or the then most senior securities issued by Plurinuva, in consideration for such amount equal to 200% of the remaining balance of the aggregate purchase price of the First Warrant, provided that Tnuva exercises at least 62,500 ordinary shares at a price per share of \$40.00, or \$2,500 in the aggregate, of the First Warrant. The Second Warrant's exercise price per share equals \$76.00. The Second Warrant has a term commencing on the six months anniversary of the Closing Date and ending at the earlier of (i) six months from its issuance, (ii) immediately prior to and subject to the consummation of an initial public offering or acquisition of Plurinuva or (iii) the consummation of a financing round with a non-affiliated investor.

The Company allocated the consideration received in the total amount of \$7,500 between the ordinary shares and the warrants of Plurinuva issued to Tnuva such that the consideration allocated to the ordinary shares is \$6,718 and consideration allocated to the warrants is \$782.

For this purpose, the Company determined the fair value of the ordinary shares and the warrants utilizing a Monte Carlo simulation model (Level 3 classification), which incorporates various assumptions including expected stock price volatility, risk-free interest rates, and the expected date of a qualifying event. The Company estimated the volatility of the ordinary shares of Plurinuva based on data from similar companies operating in the food tech field.

The main assumptions used in the Monte Carlo simulation model are as follows:

Risk-free interest rate	1.08%
Expected stock price volatility	<u>85%</u>

The consideration allocated to the shares issued was divided between the non-controlling interests ("NCI") and the Company's shareholders as this transaction is a transaction with the NCI.

The consideration allocated to the warrants was recognized against the NCI.

- d. On February 26, 2022, Pluristem Ltd allocated a total of 45,936 of its shares in Plurinuva, which constitute approximately 3.87% of Plurinuva's ordinary shares, to its Chairman, Chief Executive Officer and Chief Financial Officer, pursuant to the terms of their respective employment and/or consulting agreements with the Company. Following such allocation the Company holds 80.34% in Plurinuva. As a result, the Company recognized compensation expenses in the amount of \$1,646 representing the fair value of the respective allocated shares.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES

a. Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of U.S. Securities and Exchange Commission Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair statement have been included (consisting only of normal recurring adjustments). For further information, reference is made to the consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended June 30, 2021. The year-end balance sheet data was derived from the audited consolidated financial statements as of June 30, 2021, but not all disclosures required by U.S. GAAP are included.

Operating results for the nine-month period ended March 31, 2022 are not necessarily indicative of the results that may be expected for the year ending June 30, 2022.

b. Significant Accounting Policies

The significant accounting policies followed in the preparation of these unaudited interim condensed consolidated financial statements are identical to those applied in the preparation of the latest annual financial statements.

c. Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates, judgments and assumptions that are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. Principles of consolidation

The consolidated financial statements include Plurinuva, an entity in which the Company owns less than 100%. The outside shareholders’ interests are shown as non-controlling interests in equity. Changes in ownership interests in subsidiaries that do not result in a change of control of the subsidiary by the Company are presented as equity transactions. Intercompany transactions and balances are eliminated on consolidation.

e. Fair value of financial instruments

The carrying amounts of the Company’s financial instruments, including cash and cash equivalents, short-term and restricted bank deposits, accounts receivable and other current assets, trade payable and other accounts payable, accrued expenses and other liabilities, approximate fair value because of their generally short-term maturities.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company measures its derivative instruments at fair value under Accounting Standards Codification (“ASC”), “Fair Value Measurements and Disclosures” (“ASC 820”). Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly;
and

Level 3 - Unobservable inputs for the asset or liability.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company categorized each of its fair value measurements in one of these three levels of hierarchy.

The Company measures its liability pursuant to the Finance Agreement with the EIB based on the aggregate outstanding amount of the combined principal and accrued interest. The Company does not reflect its liability for future royalty payments pursuant to the Finance Agreement with the EIB since the royalty payments are to be paid as a percentage of the Company’s future consolidated revenues, pro-rated to the amount disbursed, beginning in the fiscal year 2024 and continuing up to and including its fiscal year 2030, which cannot be measured at this time.

f. Recently Issued Accounting Pronouncements

ASU No. 2016-13 - “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” (“ASU 2016-13”):

In June 2016, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” (“ASU 2016-13”). ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans, and other instruments, entities will be required to use a new forward-looking “expected loss” model that generally will result in the earlier recognition of allowances for losses.

The guidance also requires increased disclosures. The amendments contained in ASU 2016-13 were originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years for the Company. In November 2019, the FASB issued ASU No. 2019-10, which delayed the effective date of ASU 2016-13 for smaller reporting companies (as defined by the U.S. Securities and Exchange Commission, “SRC”) to fiscal years beginning after December 15, 2022, including interim periods. Early adoption is permitted. The Company meets the definition of a SRC and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently

evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements but does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

ASU No. 2021-10- " Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance" ("ASU 2021-10"):

In November 2021, the FASB issued ASU 2021-10, "Government Assistance (Topic 832)," which requires business entities to disclose information about transactions with a government that are accounted for by applying a grant or contribution model by analogy (for example, IFRS guidance in IAS 20 or guidance on contributions for not-for-profit entities in ASC 958-605). For transactions within scope, the new standard requires the disclosure of information about the nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement line items affected by the transaction. The new guidance is effective for annual reporting periods beginning after December 15, 2021. The Company is currently evaluating the effect the adoption of this ASU may have on our future disclosures.

NOTE 3: - COMMITMENTS AND CONTINGENCIES

- a. As of March 31, 2022, an amount of \$1,139 of cash and deposits was pledged by the Subsidiary to secure its credit line and bank guarantees related to its facility operating lease agreement.
- b. Under the Law for the Encouragement of Industrial Research and Development, 1984, (the "Research Law"), research and development programs that meet specified criteria and are approved by the IIA are eligible for grants of up to 50% of the project's expenditures, as determined by the research committee, in exchange for the payment of royalties from the sale of products developed under the program. Regulations under the Research Law generally provide for the payment of royalties to the IIA of 3% on sales of products and services derived from a technology developed using these grants until 100% of the dollar-linked grant is repaid. The Company's obligation to pay these royalties is contingent on its actual sale of such products and services. In the absence of such sales, no payment is required. Outstanding balance of the grants will be subject to interest at a rate equal to the 12 month LIBOR applicable to dollar deposits that is published on the first business day of each calendar year. Following the full repayment of the grant, there is no further liability for royalties.

Through March 31, 2022, total grants from the IIA obtained aggregated to approximately \$27,743 and total royalties paid and accrued amounted to \$169. As of March 31, 2022, the Company's contingent liability in respect to royalties to the IIA amounted to \$27,574, not including LIBOR interest as described above.

- c. The Company has been awarded a marketing grant under the "Smart Money" program of the Israeli Ministry of Economy and Industry. The program's aim is to assist companies to extend their activities in international markets. The goal market that was chosen was Japan. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in Japan and for regulatory activities there. As part of the program, the Company will repay royalties of 5% from the Company's income in Japan over a five-year period, starting the year in which, the Company will not be entitled to reimbursement of expenses under the program and will be spread over a period of up to 5 years or until the amount of the grant is fully paid.

As of March 31, 2022, total grants obtained under this Smart Money program amounted to approximately \$112. As of March 31, 2022, the Company's contingent liability with respect to royalties for this "Smart Money" program was \$112 and no royalties were paid or accrued.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 3: - COMMITMENTS AND CONTINGENCIES (CONT.)

- d. The Company was awarded an additional Smart Money grant of approximately \$229 from Israel's Ministry of Economy and Industry to facilitate certain marketing and business development activities with respect to its advanced cell therapy products in the Chinese market, including Hong Kong. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in the China-Hong Kong markets. The Company will also receive close support from Israel's trade representatives stationed in China, including Hong Kong, along with experts appointed by the Smart Money program. As part of the program, the Company will repay royalties of 5% from the Company's revenues in the region over a five-year period, beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread over a period of up to 5 years or until the amount of the grant is fully paid.

As of March 31, 2022, the aggregate amount of grant obtained from this Smart Money program was approximately \$178. As of March 31, 2022, the Company's contingent liability with respect to royalties for this "Smart Money" program is \$178 and no royalties were paid or accrued.

- e. In September 2017, the Company signed an agreement with the Tel-Aviv Sourasky Medical Center (Ichilov Hospital) to conduct a Phase I/II trial of PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease ("cGvHD").

As part of the agreement with the Tel-Aviv Sourasky Medical Center (Ichilov Hospital), the Company will pay royalties of 1% from its net sales of the PLX-PAD product relating to cGvHD, with a maximum aggregate royalty amount of approximately \$250.

- f. The Company was awarded a marketing grant of approximately \$52 under the "Shalav" program of the Israeli Ministry of Economy and Industry. The grant is intended to facilitate certain marketing and business development activities with respect to the Company's advanced cell therapy products in the U.S. market. As part of the program, the Company will repay royalties of 3%, but only with respect to the Company's revenues in the U.S. market in excess of \$250 of its revenues in fiscal year 2018, upon the earlier of the five year period beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and/or until the amount of the grant, which is linked to the Consumer Price Index, is fully paid.

As of March 31, 2022, total grants obtained under the "Shalav" program amounted to approximately \$52. As of March 31, 2022, the Company's contingent liability with respect to royalties for this "Shalav" program was \$52 and no royalties were paid or accrued.

- g. In December 2021, the Company signed an addendum to its facility operating lease agreement (the "Addendum") with the lessor, which extended the lease period to December 2026 and the Company has the option to extend the term of the lease (the "Extension Option") for an additional period of five years until December 2031. The monthly lease payments are approximately \$94 (291,000 NIS) and will increase by 10% with the Extension Option. As a result of the Addendum, the right of use asset in the amount of \$8,353 is presented in the long-term assets, and the operating lease liability in the amount of \$669 and \$7,271 is presented in the short-term and long-term liabilities, respectively. The appropriate discount rate for the Company's operating lease is 9.2%. The Company recognizes lease expenses, on a straight-line basis over the lease term.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 4: - LOAN FROM THE EIB

On April 30, 2020, Pluristem GMBH entered into a finance agreement (the “Finance Agreement”) with the EIB, pursuant to which Pluristem GmbH can obtain a loan in the amount of up to €50 million, subject to certain milestones being reached (the “Loan”), payable in three tranches, with the first tranche consisting of €20 million, the second of €18 million and the third of €12 million for a period of 36 months from the signing of the Finance Agreement.

The tranches will be treated independently, each with its own interest rate and maturity period. The interest rate is 4% in the aggregate (consisting of a 0% fixed interest rate and a 4% deferred interest rate payable upon maturity, respectively) per year for the first tranche, 4% in the aggregate (consisting of a 1% fixed interest rate and a 3% deferred interest rate payable upon maturity, respectively) per year for the second tranche and 3% (consisting of a 1% fixed interest rate and a 2% deferred interest rate payable upon maturity, respectively) per year for the third tranche.

In addition to any interest payable on the Loan, the EIB is entitled to receive royalties from future revenues, if any, of Pluristem for a period of seven years starting in 2024, in an amount equal to between 0.2% to 2.3% of the Company’s consolidated revenues, pro-rated to the amount disbursed from the Loan to Pluristem beginning in the fiscal year 2024 and continuing up to and including its fiscal year 2030.

During June 2021, Pluristem received the first tranche in an amount of \$24,449 (€20 million) of the Finance Agreement. The amount received is due on June 1, 2026 and bears annual interest of 4% to be paid with the principal of the Loan. As of March 31, 2022, the linked principal balance in the amount of \$22,189 (due to exchange rate differences), and the interest accrued in the amount of \$735 are presented as part of the Loan as long-term liabilities.

NOTE 5: - SHAREHOLDERS’ EQUITY

Pursuant to a shelf registration statement on Form S-3, declared effective by the SEC on July 23, 2020, in July 2020 the Company entered into an Open Market Sale Agreement (“ATM Agreement”) with Jefferies LLC (“Jefferies”), which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell common shares having an aggregate offering price of up to \$75,000 through Jefferies acting as sales agent. During the year ended June 30, 2021, the Company sold 1,045,097 common shares under the ATM Agreement at an average price of \$8.50 per share for aggregate net proceeds of approximately \$8,506, net of issuance expenses of \$380. There were no sales under the ATM Agreement during the nine months ended March 31, 2022.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 5: - SHAREHOLDERS' EQUITY (CONT.)

a. Options to consultants:

A summary of the options to non-employee consultants under the Company's 2005 and 2016 equity incentive plans is as follows:

	Nine months ended March 31, 2022			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at the beginning of the period	39,836	\$ -	6.99	\$ 158
Options granted	40,000	\$ 2.33		
Options forfeited	(1,291)	\$ -		
Options outstanding at the end of the period	<u>78,545</u>	<u>\$ 1.24</u>	<u>8.08</u>	<u>\$ 82</u>
Options exercisable at the end of the period	<u>36,670</u>	<u>\$ -</u>	<u>6.44</u>	<u>\$ 76</u>
Options unvested	<u>41,875</u>	<u>\$ 2.32</u>		
Options vested and expected to vest	<u>78,545</u>	<u>\$ 1.24</u>	<u>8.08</u>	<u>\$ 82</u>

Compensation expenses recorded in general and administration expenses related to options granted to consultants for the nine and three months ended March 31, 2022 and 2021 were \$29 and \$19, \$9 and \$3, respectively.

b. **Restricted Shares units ("RSUs") to employees, directors and consultants:**

1. RSUs to employees and directors:

The following table summarizes the activity related to RSUs granted to employees and directors under the Company's 2005, 2016 and 2019 equity incentive plans for the nine-month periods ended March 31, 2022 and 2021:

	Nine months ended March 31,	
	2022	2021
	Number	
Unvested at the beginning of the period	2,404,415	415,194
Granted	75,000	2,643,120
Forfeited	(41,028)	(39,849)
Vested	<u>(350,239)</u>	<u>(363,182)</u>

Unvested at the end of the period	<u>2,088,148</u>	<u>2,655,283</u>
Expected to vest after the end of the period	<u>2,052,240</u>	<u>2,611,578</u>

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARIES

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)

NOTE 5: - SHAREHOLDERS' EQUITY (CONT.)

Compensation expenses related to RSUs granted to employees and directors were recorded as follows:

	Nine months ended March 31,		Three months ended March 31,	
	2022	2021	2022	2021
Research and development expenses	\$ 526	\$ 1,158	\$ 108	\$ 594
General and administrative expenses	*7,032	8,962	*2,538	4,794
	<u>\$ 7,558</u>	<u>\$ 10,120</u>	<u>\$ 2,646</u>	<u>\$ 5,388</u>

Unamortized compensation expenses related to RSUs granted to employees and directors is approximately \$4,196 to be recognized by the end of December 2025.

*Including compensation expenses in the amount of \$1,646 related to Plurinuva's ordinary shares pursuant to employment/ consulting agreement (see note 1d).

2. RSUs to consultants:

The following table summarizes the activity related to unvested RSUs granted to consultants under the Company's 2005, 2016 and 2019 equity incentive plans for the nine-month periods ended March 31, 2022 and 2021:

	Nine months ended March 31,	
	2022	2021
	Number	
Unvested at the beginning of the period	76,249	6,250
Granted	-	110,000
Forfeited	-	(29,062)
Vested	(34,375)	(10,313)
Unvested at the end of the period	<u>41,874</u>	<u>76,875</u>

Compensation expenses related to RSUs granted to consultants were recorded as follows:

	Nine months ended March 31,		Three months ended March 31,	
	2022	2021	2022	2021
Research and development expenses	\$ 46	\$ 142	\$ 1	\$ 74
General and administrative expenses	149	111	55	60
	<u>\$ 195</u>	<u>\$ 253</u>	<u>\$ 56</u>	<u>\$ 134</u>

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws, and is subject to the safe-harbor created by such Act and laws. Forward-looking statements may include statements regarding our goals, beliefs, strategies, objectives, plans, including product and technology developments, future financial conditions, results or projections or current expectations. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” or “continue,” the negative of such terms, or other variations thereon or comparable terminology. These statements are merely predictions and therefore inherently subject to known and unknown risks, uncertainties, assumptions and other factors that may cause actual results, performance levels of activity, or our achievements, or industry results to be materially different from those contemplated by the forward-looking statements. Such forward-looking statements appear in this Item 2 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and may appear elsewhere in this Quarterly Report on Form 10-Q and include, but are not limited to, statements regarding the following:

- the expected development and potential benefits from our products in treating various medical conditions;
- our entering into certain contracts with third parties;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies, research organizations and medical institutions, including, without limitation Tnuva (as defined below);
- our pre-clinical and clinical trials plans, including timing of initiation, expansion, enrollment, results, and conclusion of trials;
- achieving regulatory approvals, including under accelerated paths;
- receipt of future funding from the Israel Innovation Authority, or IIA, the European Union’s Horizon programs, as well as grants from other independent third parties;
- the receipt of additional funds pursuant to our finance agreement, or the EIB Finance Agreement, with the European Investment Bank, or the EIB, and whether we will achieve further milestones necessary to receive additional funds thereunder;
- developing capabilities for new clinical indications of placenta expanded, or PLX, cells and new products;
- the progress of our multinational Phase III trial program for the potential use of PLX cells in the treatment of muscle injury following arthroplasty for hip fracture;
- our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;
- the possible impacts of cybersecurity incidents on our business and operations;
- our expectations regarding our short- and long-term capital requirements;

- our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses;
- information with respect to any other plans and strategies for our business; and
- our expectations regarding the impact of the COVID-19 pandemic, including on our clinical trials and operations.

Our business and operations are subject to substantial risks, which increase the uncertainty inherent in the forward-looking statements contained in this report.

In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this periodic report would be interpreted differently in light of additional research, clinical and preclinical trials results. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading “Risk Factors” in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended June 30, 2021, or the 2021 Annual Report, as well as Item 1A of this Quarterly Report. Readers are also urged to carefully review and consider the various disclosures we have made in that report.

As used in this Quarterly Report on Form 10-Q, the terms “we”, “us”, “our”, the “Company” and “Pluristem” mean Pluristem Therapeutics Inc. and our wholly owned subsidiaries, Pluristem Ltd. and Pluristem GmbH, and our subsidiary Plurinuva Ltd., unless otherwise indicated or as otherwise required by the context.

Overview

We are a biotechnology company with an advanced cell-based technology platform. We have developed a unique three-dimensional, or 3D, technology platform for cell expansion with an industrial scale in-house GMP cell manufacturing facility. We are utilizing our technology in the field of regenerative medicine and food tech and plan to utilize it in other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform.

Our operations are focused on the research, development and manufacturing of cells, conducting clinical studies and the business development of cell therapeutics and cell based technologies, such as our recent collaboration with Tnuva Food Industries – Agricultural Cooperative in Israel Ltd., through its fully owned subsidiary, Tnuva Food-Tech Incubator (2019), Limited Partnership, or Tnuva, to use our technology to establish a cultured food platform.

We use our advanced cell-based technology platform in the field of regenerative medicine to develop placenta-based cell therapy product candidates for the treatment of inflammatory, muscle injuries and hematologic conditions. We develop, and intend to commercialize, cell therapy production technologies and products that are derived from the human placenta after a full-term delivery of a healthy baby. Our placental expanded, or PLX, cells are adherent stromal cells that are expanded using our 3D platform. Our PLX cells can be administered to patients off-the-shelf, without blood or tissue matching or additional manipulation prior to administration. PLX cells are believed to release a range of therapeutic proteins in response to the patient’s condition.

We intend to enhance the global reach of our cell expansion technology and PLX product portfolio, enabling the development of various new cell-based products for multiple applications, based on our innovative technology and manufacturing capabilities. Our goal is to make significant progress with our clinical pipeline and clinical studies to ultimately bring innovative, potent therapies to patients who need new treatment options.

In addition, we plan to continue leveraging our proprietary technology for other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform, such as the food tech industry. We expect to demonstrate a real-world impact and value from our cell based technology platform and PLX pipeline. Our business model for commercialization and revenue generation includes, but is not limited to, licensing deals, joint ventures, direct sale of our products and partnerships.

Clinical Studies

We are conducting several multinational clinical studies which consist of a Phase III clinical study in muscle recovery following surgery for hip fracture and two Phase II clinical studies in Acute Respiratory Distress Syndrome, or ARDS, associated with COVID-19 in the United States, Europe and Israel. In addition, we are focusing on other clinical programs in the hematological field such as a Phase I clinical study for incomplete recovery following bone marrow transplantation in the United States and Israel, an investigator-led Phase I/II Chronic Graft versus Host Disease study in Israel, and Acute Radiation Syndrome, or ARS, under the U.S. Food and Drug Administration, or FDA, animal rule. We believe that each of these indications is a severe unmet medical need.

On November 15, 2021, we announced that we fully completed the enrollment of 240 patients for our Phase III clinical study in muscle recovery following surgery for hip fracture. The multinational clinical study includes patients from the U.S., Europe, and Israel, and we expect to announce topline results in the third calendar quarter of 2022.

On December 27, 2021, we announced topline results for our COVID-19 studies based on 89 patients enrolled. The primary efficacy endpoint was the number of ventilator free days, or VFD, from day 1 through day 28 of the studies. VFD at day 60 and all-cause mortality at days 28 and 60 were part of the secondary efficacy endpoints in the studies. The studies did not meet the primary efficacy endpoint of statistically significant improvement of VFD at 28 days. Taking into consideration the baseline risk factors of the ARDS patients, no differences in the safety profile were observed between PLX-PAD and placebo.

We have completed enrollment of 21 patients in our first in human Phase I clinical study in incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT, in the United States and Israel. The study is designed to assess the safety and efficacy of PLX-R18. In March 2022, we announced positive final results for this Phase I study.

Data collected over twelve months post-treatment with PLX-R18 demonstrated that (i) PLX-R18 was well-tolerated with a favorable safety profile; (ii) patients treated with PLX-R18 showed an increase in all three blood cell types compared to baseline with platelets ($p < 0.001$), hemoglobin ($p = 0.01$) and neutrophils ($p = 0.15$) levels increasing as early as one month following PLX-R18 administration and enduring up to twelve months following treatment; (iii) following PLX-R18 treatment, the number of transfused units decreased from a mean monthly number of 5.09 for platelets and 2.91 for red blood cells at baseline to 0.55 for platelets and 0 for red blood cells ($p = 0.0005$) at twelve months; and (iv) the observed annual mortality rate following PLX-R18 administration was 18% compared to 29% in a cohort of allogeneic HCT recipients with incomplete hematopoietic recovery, obtained from the Center for International Blood and Marrow Transplant Research registry, representing a similar patient population.

Our manufacturing facility complies with the European, Japanese, Israeli, South Korean and the FDA's current Good Manufacturing Practice, or cGMP, requirements and has been inspected and approved by the European Qualified Person, or QP, and Israeli MoH for production of PLX cells for late stage trials. We have also been granted manufacturer/importer authorization and cGMP Certification by the Israeli Ministry of Health. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow PLX cells in commercial quantities.

Food Tech

On January 5, 2022, we signed definitive collaboration agreements with Tnuva through our fully owned subsidiary Pluristem Ltd., or the Subsidiary. Under the definitive collaboration agreements, or the Joint Venture Agreement, we established a new company, Plurinuva Ltd., an Israeli company, or Plurinuva, with the purpose of developing cultured meat products of all types and kinds. Plurinuva is intended to be engaged in the development, manufacturing and commercialization of technology, know-how and products that will be based on licensed products, or the Licensed Products, relating to the field of cultured meat, or the Field.

Pursuant to the Joint Venture Agreement, Tnuva entered into a share purchase agreement, or the SPA, with Plurinuva and the Subsidiary, pursuant to which Plurinuva issued on the closing date of the SPA, or the Closing Date, 15.79% of its share capital to Tnuva, as well as a warrant to purchase additional shares of Plurinuva, in consideration of an aggregate of \$7,500,000 in cash. In addition, pursuant to the SPA, in the event the Company decides to use its technology for the development of cultured milk or fish products, Tnuva shall also have the right, for a period of seven years following the Closing Date, to participate in the formation of additional separate joint ventures for the development of those products.

On February 24, 2022, we announced the closing of the Joint Venture Agreement and the SPA, and on March 8, 2022, we announced the appointment of Eyal Rosenthal as Chief Executive Officer of Plurinuva.

Prior to the Closing Date, the Subsidiary and Plurinuva also executed a technology license agreement, or the License Agreement, and on the Closing Date, the Subsidiary and Plurinuva executed a transitional services agreement, or the Services Agreement. Pursuant to the License Agreement, the Subsidiary granted Plurinuva an exclusive, royalty bearing, perpetual and irrevocable, worldwide, non-transferable (except under specific circumstances specified thereunder), sublicensable license to its technology for the use in the development of the Licensed Products in the field of cultured meat, or the Field. In addition, Plurinuva shall grant the Subsidiary, pursuant to the License Agreement, an exclusive, perpetual and irrevocable, worldwide, sublicensable, royalty-free, license to use, make, exploit and develop the improvements made by Plurinuva to the licensed technology outside of the Field. In consideration for the license, Plurinuva agreed to grant the Subsidiary royalties from its future net sales in the mid-single digits. Pursuant to the terms of the Services Agreement, the Subsidiary shall provide Plurinuva transitional services to support its development efforts, for an initial term of eighteen months, subject to mutual extension for an additional six months.

Pursuant to the SPA, Tnuva and Plurinuva agreed to enter into a commercialization agreement within twelve months pursuant to which Tnuva shall be granted exclusive marketing, distribution and sale rights of the Licensed Products in Israel. Tnuva's exclusivity in the region will be subject to achieving and maintaining specific milestones. Plurinuva shall retain exclusive worldwide marketing, distribution, and sale rights for the Licensed Products worldwide, except in Israel.

On February 26, 2022, Pluristem Ltd. allocated a total of 45,936 of its shares in Plurinuva, which constitute approximately 3.87% of its holdings in Plurinuva, to our Chairman, Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, pursuant to the terms of their respective employment and/or consulting agreements with the Company.

Cybersecurity Incident

As previously reported in our Quarterly Report on Form 10-Q for the period ended December 31, 2021, during November 2021, we experienced a cybersecurity incident in which one or more third parties were able to impersonate one of our vendors by using a falsified email domain account and asked to make a payment to a false bank account. As a result of this incident, the third parties managed to extract a sum of approximately \$616,000 from us. As a result of this incident, we immediately launched an investigation into the incident, hired the services of a cybersecurity investigation firm to fully access the incident and notified the appropriate government authorities, including the banks involved in the transaction.

During February 2022, with the assistance of local and global law enforcement agencies, we were able to recover an amount of approximately \$412,000 from the false bank account. Together with the reimbursement received from our insurance company we were able to recover the full amount lost.

The cybersecurity incident has not had any effect on our ability to meet our financial obligations, including our ability to carry out our operations and business activities. In addition, our investigation has confirmed that, other than the funds referenced above, none of our information or data was stolen or damaged. Nonetheless, our security protections, including the steps we have taken in response to the November 2021 incident, may not prevent future incidents of a similar nature or other cyber-attacks. We are constantly exploring new and advanced security protection measures to prevent future cybersecurity incidents.

RESULTS OF OPERATIONS – THREE AND NINE MONTHS ENDED MARCH 31, 2022 COMPARED TO THREE AND NINE MONTHS ENDED MARCH 31, 2021.

Revenues

Revenues for the nine-month and three-month periods ended March 31, 2022 were \$234,000, as compared to no revenues, during the nine-month and three-month periods ended March 31, 2021. Revenues for the nine-month and three-month periods ended March 31, 2022 were related to the sale of our PLX cells for research use and proceeds related to a license agreement we signed with Takeda Pharmaceuticals International AG, or Takeda, a company based in Switzerland and operates in the field of adipose-derived cells, under which we granted Takeda a global, non-exclusive license to use several of our patents, limited to adipose fat cells only in the field of therapeutics. The license covers methods for expanding adherent stromal cells and specified second medical uses.

Research and Development Expenses, Net

Research and development expense, net (costs less participation and grants by the Horizon 2020 program, the IIA and other parties) for the nine-month period ended March 31, 2022 decreased by 12% from \$21,581,000 for the nine-month period ended March 31, 2021 to \$19,016,000. The decrease is mainly attributed to a decrease in clinical trial subcontractor expenses following the termination of our critical limb ischemia, or CLI, study, end of enrollment of our Phase II studies of ARDS associated with COVID-19 and a decrease in share-based compensation expenses related to restricted stock units, or RSUs granted to employees and consultants. The decrease was partially offset by increased payroll expenses related to payroll adjustments and exchange currency adjustments, together with an increase in materials purchases to support the Company's manufacturing plan.

Research and development expense, net (costs less participation and grants by the Horizon 2020 program, the IIA and other parties) for the three-month period ended March 31, 2022 decreased by 20% from \$7,666,000 for the three-month period ended March 31, 2021 to \$6,156,000. The decrease is mainly attributed to a decrease in clinical trial subcontractor expenses following the termination of the CLI study, end of enrollment of our Phase II studies of ARDS associated with COVID-19 and a decrease in share-based compensation expenses related to RSUs granted to employees and consultants. The decrease was partially offset by an increase in materials purchases to support the Company's current manufacturing plan.

General and Administrative Expenses

General and administrative expenses for the nine-month period ended March 31, 2022 decreased by 4% from \$14,455,000 for the nine-month period ended March 31, 2021 to \$13,929,000. The decrease is mainly attributed to a decrease in share-based compensation expenses related to market based vesting conditioned RSUs granted to our CEO and Chairman, partially offset by an increase in share-based compensation expenses related to allocation of shares of Plurinuva to our CEO, CFO and Chairman pursuant to their employment or consulting agreement (see also note 1d to the interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

General and administrative expenses for the three-month period ended March 31, 2022 decreased by 31% from \$6,559,000 for the three-month period ended March 31, 2021 to \$4,553,000. The decrease is mainly attributed to a decrease in share-based compensation expenses related to market based vesting conditioned RSUs granted to our CEO and Chairman, and the cancellation of provision for losses due to a cybersecurity incident following the recovery of the funds, partially offset by an increase in share-based compensation expenses related to allocation of shares of Plurinuva to our CEO, CFO and Chairman pursuant to their employment or consulting agreement (see also note 1d to the interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Financial Income

Financial income increased from \$912,000 for the nine-month period ended March 31, 2021 to financial income of \$1,097,000 for the nine-month period ended March 31, 2022. This increase is mainly attributable to an increase in interest income on deposits, partially offset by a decrease in income from exchange rate differences on deposits linked to the NIS.

Financial income increased from \$125,000 for the three-month period ended March 31, 2021 to financial income of \$678,000 for the three-month period ended March 31, 2022. This increase is mainly attributable to an increase in income from exchange rate differences of the Euro against the U.S. dollar, primarily related to the EIB loan provided to us pursuant to the EIB Finance Agreement, additional financial income from exchange rate differences related to the renewal of our operating lease agreement and the effect of implementing the leasing accounting standard.

Financial Expenses

Financial expenses increased from \$173,000 for the nine-month period ended March 31, 2021 to financial expenses of \$676,000 for the nine-month period ended March 31, 2022. This increase is mainly attributable to interest expenses related to the EIB loan provided to us pursuant to the EIB Finance Agreement.

Financial expenses decreased from \$154,000 for the three-month period ended March 31, 2021 to financial expenses of \$121,000 for the three-month period ended March 31, 2022. This decrease is mainly attributable to exchange rate differences due to the strength of the NIS against the U.S. dollar on cash and deposits linked to the NIS, partially offset by interest expenses related to the EIB loan provided to us pursuant to the EIB Finance Agreement.

Net Loss

Net loss for the nine and three-month periods ended March 31, 2022 was \$32,290,000 and \$9,918,000 respectively, as compared to net loss of \$35,297,000 and \$14,254,000 for the nine and three-month periods ended March 31, 2021. For the nine-month period, the decrease was mainly due to a decrease in research and development expenses, net, and for the three-month period the decrease was due to a decrease in general and administrative expenses and research and development expenses, as described above. Net loss per share for the nine and three-month periods ended March 31, 2022 was \$1.00 and \$0.31, respectively, as compared to \$1.31 and \$0.48, respectively for the nine and three-month periods ended March 31, 2021. We had net loss attributed to our non-controlling interest in Plurinuva for the nine and three-month periods ended March 31, 2022 of \$53,000.

For the nine and three-month periods ended March 31, 2022 and March 31, 2021, we had weighted average common shares outstanding of 32,131,503, 32,261,628, and 26,936,831, 29,617,233, respectively, which were used in the computations of net loss per share for the nine and three-month periods.

The increase in weighted average common shares outstanding reflects the issuance of additional shares mainly related to the issuances of shares pursuant to a securities purchase agreement with certain institutional investors in February 2021, issuances of shares pursuant to our Open Market Sale AgreementTM, or the ATM Agreement, that we entered into with Jefferies LLC, or Jefferies, on July 16, 2020, issuances of additional shares upon the settlement of RSUs issued to directors, employees and consultants, and shares issued as a result of exercises of outstanding warrants and options.

Liquidity and Capital Resources

As of March 31, 2022, our total current assets were \$64,313,000 and total current liabilities were \$7,822,000. On March 31, 2022, we had a working capital surplus of \$56,491,000, total equity of \$40,143,000, out of which \$2,050,000 is attributed to the non-controlling interest in Plurinuva, and an accumulated deficit of \$362,258,000.

Our cash and cash equivalents as of March 31, 2022 amounted to \$23,791,000, compared to \$12,265,000 as of March 31, 2021, and compared to \$31,241,000 as of June 30, 2021. Cash balances changed in the nine months ended March 31, 2022 and 2021 for the reasons presented below.

Operating activities used cash of \$28,074,000 in the nine months ended March 31, 2022, compared to \$21,313,000 in the nine months ended March 31, 2021. The increase is mainly attributed to payments made to our suppliers, an increase in payments to our employees and the strength of the NIS against the U.S. Dollar. Cash used in operating activities in the nine months ended March 31, 2022 and 2021 consisted primarily of payments of fees to our suppliers, subcontractors, professional services providers and consultants, including the costs of our clinical studies, and payments of salaries to our employees, partially offset by grants from the IIA, the EU's Horizon 2020 program, Israel's Ministry of Economy and other research grants.

Investing activities provided cash of \$14,738,000 in the nine months ended March 31, 2022, compared to cash used of \$12,057,000 for the nine months ended March 31, 2021. The investing activities in the nine-month period ended March 31, 2022 consisted primarily of withdrawal of \$19,052,000 of long-term deposits, partially offset by the investment of \$4,233,000 in short-term deposits and payments of \$81,000 related to investments in property and equipment. The investing activities in the nine-month period ended March 31, 2021, consisted primarily of the investment of \$13,688,000 in long term deposits and payments of \$331,000 related to investments in property and equipment, partially offset by the withdrawal of \$1,962,000 of short-term deposits.

Financing activities provided cash of \$7,500,000 during the nine months ended March 31, 2022, compared to \$36,992,000 for the nine months ended March 31, 2021. The cash generated in the nine months ended March 31, 2022 from financing activities was related to net proceeds of \$7,500,000 received from investment in Plurinuva. The cash generated in the nine months ended March 31, 2021 from financing activities was related to net proceeds of \$36,628,000 comprised of funds received from our February 2021 registered direct offering and issuances made under the ATM Agreement and net proceeds of \$364,000 from the exercise of warrants.

On July 16, 2020, we entered into the ATM Agreement with Jefferies, pursuant to which we may issue and sell our common shares having an aggregate offering price of up to \$75,000,000 from time to time through Jefferies. Upon entering into the ATM Agreement, we filed a new shelf registration statement on Form S-3, which was declared effective by the SEC on July 23, 2020. During the year ended June 30, 2021, we sold 1,045,097 of our common shares under the ATM Agreement at an average price of \$8.50 per share for aggregate net proceeds of approximately \$8,506,000. During the nine months ended March 31, 2022, we did not sell any of our common shares under the ATM Agreement.

In April 2020, we and our subsidiaries, Pluristem Ltd. and Pluristem GmbH, executed the EIB Finance Agreement for non-dilutive funding of up to €50 million in the aggregate, payable in three tranches. The proceeds from the EIB Finance Agreement are intended to support our research and development in the European Union to further advance our regenerative cell therapy platform, and to bring the products in our pipeline to market. The proceeds from the EIB Finance Agreement are expected to be deployed in three tranches, subject to the achievement of certain clinical, regulatory and scaling up milestones.

During June 2021, we received the first tranche in the amount of €20 million pursuant to the EIB Finance Agreement. The amount received is due to be repaid on June 1, 2026 and bears annual interest of 4% to be paid together with the principal of the loan. As of March 31, 2022, the interest accrued was in the amount of €663,000. In addition to the interest payable, the EIB is also entitled to royalty payments, pro-rated to the amount disbursed from the EIB loan, on the Company's consolidated revenues beginning in the fiscal year 2024 up to and including its fiscal year 2030, in an amount equal to up to 2.3% of the Company's consolidated revenues below \$350 million, 1.2% of the Company's consolidated revenues between \$350 million and \$500 million and 0.2% of the Company's consolidated revenues exceeding \$500 million.

According to the IIA grant terms, we are required to pay royalties at a rate of 3% on sales of products and services derived from technology developed using this and other IIA grants until 100% of the dollar-linked grants amount plus interest are repaid. In the absence of such sales, no payment is required. Through March 31, 2022, total grants obtained from the IIA aggregated to approximately \$27,743,000 and total royalties paid and accrued amounted to \$169,000.

In June 2020, we announced that we were selected as a member of the CRISPR-IL consortium, a group funded by the IIA. CRISPR-IL brings together the leading experts in life science and computer science from academia, medicine, and industry, to develop Artificial Intelligence, or AI, based end-to-end genome-editing solutions. These next-generation, multi-species genome editing products for human, plant, and animal DNA, have applications in the pharma, agriculture, and aquaculture industries. CRISPR-IL is funded by the IIA with a total budget of approximately \$10,000,000 of which, an amount of approximately \$480,000 was a direct grant allocated to us, for the initial period of 18 months. During October 2021, we received an approval for an additional grant of approximately \$583,000 from the IIA pursuant to the CRISPR-IL consortium program, for an additional period of eighteen months.

Through March 31, 2022, we received total grants of approximately \$694,000 in cash from the IIA pursuant to the CRISPR-IL consortium program, out of which an amount of \$293,000 was received during the nine-months ended March 31, 2022.

The currency of our financial portfolio is mainly in U.S. dollars and we use options contracts and other financial instruments in order to hedge our exposures to currencies other than the U.S. dollar. For more information, please see Item 7A. - "Quantitative and Qualitative Disclosures about Market Risk" in the 2021 Annual Report.

We have an effective Form S-3 registration statement (File No. 333-239890), filed under the Securities Act of 1933, as amended, with the SEC using a "shelf" registration process. Under this shelf registration process, we may, from time to time, sell our common shares, preferred shares and warrants to purchase common shares, and units of two or more of such securities in one or more offerings up to a total dollar amount of \$250,000,000. As of May 4, 2022, other than the \$75,000,000 of common shares we are eligible to sell pursuant to the ATM Agreement, and the \$30,000,000 of common shares we sold in a registered direct offering in February 2021, no securities have been sold pursuant to our effective Form S-3 registration statement.

Outlook

We have accumulated a deficit of \$362,258,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. Our cash needs may increase in the foreseeable future. We expect to generate revenues, from the sale of licenses to use our technology or products, but in the short and medium terms will unlikely exceed our costs of operations.

We may be required to obtain additional liquidity resources in order to support the commercialization of our products and maintain our research and development and clinical trials activities.

We are continually looking for sources of funding, including non-diluting sources such as the EIB Finance Agreement, grants from the IIA, EU's Horizon 2020 program, Israel's Ministry of Economy and other research grants, collaboration with other companies, establishment of new ventures and sales of our common shares.

We believe that we have sufficient cash to fund our operations for at least the next 12 months.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures - We maintain a system of disclosure controls and procedures that are designed for the purposes of ensuring that information required to be disclosed in our SEC reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our CEO and our CFO, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures are effective.

Changes in Internal Control Over Financial Reporting – There has been no change in our internal control over financial reporting during the third quarter of fiscal year 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 6. Exhibits.

- 10.1*[^] [Share Purchase Agreement, dated January 5, 2022, by and among Tnuva Food-Tech Incubator \(2019\), Limited Partnership, Plurinuva Ltd. and Pluristem Ltd.](#)
- 10.2*[^] [Technology License Agreement, dated January 5, 2022, by and between Pluristem Ltd. and Plurinuva Ltd.](#)
- 31.1* [Rule 13a-14\(a\) Certification of Chief Executive Officer.](#)
- 31.2* [Rule 13a-14\(a\) Certification of Chief Financial Officer.](#)
- 32.1** [Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.](#)
- 32.2** [Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.](#)
- 101* The following materials from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 formatted in inline XBRL (eXtensible Business Reporting Language): (i) the Interim Condensed Consolidated Balance Sheets, (ii) the Interim Condensed Consolidated Statements of Operations, (iii) the Interim Condensed Statements of Changes in Shareholders' Equity, (iv) the Interim Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Interim Condensed Consolidated Financial Statements, tagged as blocks of text and in detail.
- 104* Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

[^] Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to Pluristem if publicly disclosed. Pluristem agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLURISTEM THERAPEUTICS INC.

By: /s/ Yaky Yanay
Yaky Yanay, Chief Executive Officer
and President
(Principal Executive Officer)

Date: May 9, 2022

By: /s/ Chen Franco-Yehuda
Chen Franco-Yehuda, Chief Financial
Officer
(Principal Financial Officer and
Principal Accounting Officer)

Date: May 9, 2022