

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 September 30, 2022

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

For the transition period from _____ to _____

Commission file number 001-31392

PLURI INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

98-0351734

(I.R.S. Employer
Identification No.)

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

(Address of principal executive offices)

3508409

(Zip Code)

Registrant's telephone number 011-972-74-7108600

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Shares, par value \$0.00001	PLUR	The Nasdaq Global Market

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

None.

(Title of class)

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	☐	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 ☒

State the number of shares outstanding of each of the issuer's classes of common shares as of the latest practicable date: 32,657,244 common shares issued and outstanding as of November 8, 2022.

PLURI INC. AND ITS SUBSIDIARIES
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of September 30, 2022

U.S. DOLLARS IN THOUSANDS

(Unaudited)

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INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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U.S. DOLLARS IN THOUSANDS

(Unaudited)

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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	<u>Note</u>	<u>September 30,</u> <u>2022</u>	<u>June 30,</u> <u>2022</u>
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 8,744	\$ 9,772
Short-term bank deposits		39,271	45,244
Restricted cash		653	1,007
Prepaid expenses and other current assets		1,055	1,724
<u>Total</u> current assets		<u>49,723</u>	<u>57,747</u>
LONG-TERM ASSETS:			
Restricted bank deposits		634	634
Severance pay fund		611	661
Property and equipment, net		707	739
Operating lease right-of-use asset		8,074	8,270
Other long-term assets		5	14
<u>Total</u> long-term assets		<u>10,031</u>	<u>10,318</u>
<u>Total</u> assets		<u>\$ 59,754</u>	<u>\$ 68,065</u>

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

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	Note	September 30, 2022	June 30, 2022
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		\$ 1,329	\$ 1,785
Accrued expenses		995	1,630
Operating lease liability		611	619
Accrued vacation and recuperation		791	1,053
Other accounts payable		1,292	1,742
<u>Total</u> current liabilities		<u>5,018</u>	<u>6,829</u>
LONG-TERM LIABILITIES			
Accrued severance pay		811	867
Operating lease liability		6,302	6,505
Loan from the European Investment Bank ("EIB")	4	20,722	21,678
<u>Total</u> long-term liabilities		<u>27,835</u>	<u>29,050</u>
COMMITMENTS AND CONTINGENCIES	3		
SHAREHOLDERS' EQUITY			
Share capital:	5		
Common shares, \$0.00001 par value per share: Authorized: 60,000,000 as of September 30, 2022, and June 30, 2022; Issued and outstanding: 32,634,662 and 32,507,491 shares as of September 30, 2022, and June 30, 2022, respectively.			
		*	*
Additional paid-in capital		401,576	401,302
Accumulated deficit		(377,384)	(371,263)
<u>Total</u> shareholders' equity		<u>24,192</u>	<u>30,039</u>
Non-controlling interests		2,709	2,147
<u>Total</u> equity		<u>26,901</u>	<u>32,186</u>
<u>Total</u> liabilities and equity		<u>\$ 59,754</u>	<u>\$ 68,065</u>

(*) Less than \$1

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Three months ended September 30,	
	2022	2021
Revenues	\$ 87	\$ -
Operating expenses:		
Research and development expenses	\$ (4,503)	\$ (6,391)
Less: participation by the Israeli Innovation Authority (IIA), Horizon 2020 and other parties	233	38
Research and development expenses, net	(4,270)	(6,353)
General and administrative expenses	(2,740)	(5,088)
Operating loss	(6,923)	(11,441)
Interest expenses	(194)	(228)
Other financial income, net	848	237
Total financial income, net	654	9
Net loss	\$ (6,269)	\$ (11,432)
Net loss attributed to non-controlling interest	(148)	-
Net loss attributed to shareholders	(6,121)	(11,432)
Loss per share:		
Basic and diluted net loss per share	\$ (0.19)	\$ (0.36)
Weighted average number of shares used in computing basic and diluted net loss per share	32,562,596	32,000,789

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

INTERIM CONDENSED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (UNAUDITED)

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

	Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Balance as of July 1, 2021	31,957,782	\$ (*)	\$ 387,172	\$ (330,021)	\$ 57,151
Share-based compensation to employees, directors and non- employee consultants	139,145	(*)	3,188	-	3,188
Net loss	-	-	-	(11,432)	(11,432)
Balance as of September 30, 2021	<u>32,096,927</u>	<u>\$ (*)</u>	<u>\$ 390,360</u>	<u>\$ (341,453)</u>	<u>\$ 48,907</u>

(*) Less than \$1

	Shareholders' Equity				Non- controlling Interests	Total Equity
	Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity	
	Shares	Amount				
Balance as of July 1, 2022	32,507,491	\$ (*)	\$ 401,302	\$ (371,263)	\$ 30,039	\$ 32,186
Share-based compensation to employees, directors, and non-employee consultants	127,171	(*)	659	-	659	984
Modification of warrants to non-controlling interests (note 1c)	-	-	(385)	-	(385)	-
Net loss	-	-	-	(6,121)	(6,121)	(6,269)
Balance as of September 30, 2022	<u>32,634,662</u>	<u>\$ (*)</u>	<u>\$ 401,576</u>	<u>\$ (377,384)</u>	<u>\$ 24,192</u>	<u>\$ 26,901</u>

(*) Less than \$1

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

Three months ended September 30,	
2022	2021

CASH FLOWS FROM OPERATING ACTIVITIES:

Net loss	\$ (6,269)	\$ (11,432)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	100	337
Share-based compensation to employees, directors and non-employee consultants	984	3,188
Decrease in prepaid expenses and other current assets and other long-term assets	674	277
Decrease in trade payables	(450)	(222)
Decrease in other accounts payable and accrued expenses	(1,344)	(696)
Decrease in operating lease right-of-use asset and liability	(15)	(84)
Increase in interest receivable on deposits	(493)	(340)
Effect of exchange rate changes on cash, cash equivalents, deposits and restricted cash	166	591
Long term interest payable and exchange rate differences relate to EIB loan	(957)	(406)
Accrued severance pay, net	(5)	(2)
Net cash used for operating activities	<u>\$ (7,609)</u>	<u>\$ (8,789)</u>

CASH FLOWS FROM INVESTING ACTIVITIES:

Purchase of property and equipment	\$ (73)	\$ (15)
Proceeds from withdrawal of (investment in) short-term deposits	6,466	(12,084)
Proceeds from withdrawal of long-term deposits	-	4,859
Net cash provided by (used for) investing activities	<u>\$ 6,393</u>	<u>\$ (7,240)</u>

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Three months ended September 30,	
	2022	2021
EFFECT OF EXCHANGE RATE ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(166)	(591)
Decrease in cash, cash equivalents and restricted cash	(1,382)	(16,620)
Cash, cash equivalents and restricted cash at the beginning of the period	11,413	31,838
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 10,031</u>	<u>\$ 15,218</u>
Reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets:		
Cash and cash equivalents	8,744	14,611
Restricted cash	653	607
Long-term restricted bank deposits	634	-
Total cash, cash equivalents, restricted cash and restricted bank deposits	<u>\$ 10,031</u>	<u>\$ 15,218</u>

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 1: - GENERAL

- a. Effective July 26, 2022, Pluri Inc., a Nevada corporation (“Pluri”), changed its name from Pluristem Therapeutics Inc. The Company also changed its symbol on the Nasdaq Global Market and Tel-Aviv Stock Exchange From “PSTI” to “PLUR”.

Pluri was incorporated on May 11, 2001. Pluri has a wholly owned subsidiary, Pluri Biotech 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”). Pluri, the Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Company” or “Pluri.” The Subsidiary, the German Subsidiary and Plurinuva are referred to as the “Subsidiaries.”

- b. The Company is a bio-technology company with an advanced cell-based technology platform, which operates in one business segment. The Company has developed a unique three-dimensional (“3D”) technology platform for cell expansion with an industrial scale in-house Good Manufacturing Practice cell manufacturing facility. Pluri currently uses its technology in the field of regenerative medicine and food tech and plans to utilize it in other industries and verticals that have a need for a mass scale and cost-effective cell expansion platform such as agri-tech and biologics. Pluri is focused on the research, development and manufacturing of cell-based products, conducting clinical studies and the business development of cell therapeutics and cell-based technologies providing potential solutions for various fields.

The Company has incurred an accumulated deficit of approximately \$377,384 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of September 30, 2022, the Company’s total shareholders’ equity amounted to \$24,192. During the three-month period ended September 30, 2022, the Company incurred losses of \$6,269 and its negative cash flow from operating activities was \$7,609.

As of September 30, 2022, the Company’s cash position (cash and cash equivalents, short-term bank deposits, restricted cash and restricted bank deposits) totaled \$49,302. The Company plans to continue to finance its operations from its current resources, by entering into licensing or other commercial and collaboration agreements, from grants to support its research and development activities, and from sales of its equity securities and from the proceeds received from the loan previously provided by the European Investment Bank (the “EIB”) (see also note 4). The Company’s 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 consolidated financial statements. The Company also implemented a cost reduction and efficiency plan in order to align with the change in its business strategy. There is no assurance, 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 products.

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

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 (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 month anniversary of the Closing Date, and provided that the First Warrant has not expired, Plurinuva agreed to issue a second warrant (the “Second Warrant”) to Tnuva 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 month 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 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 rate, 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 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.

On August 23, 2022, (“Amendment Date”), Plurinuva and Tnuva executed an amendment to the warrant agreement (“Amendment”), extending the exercise period of the First Warrant from six months to nine months from the Closing Date. All other terms remained unchanged.

Following the Amendment, the Company recalculated the fair value of the warrants utilizing the same Monte Carlo simulation model (Level 3 classification) before and after the Amendment Date, which incorporates various assumptions including expected stock price volatility, risk-free interest rate, and the expected date of a qualifying event.

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

Risk-free interest rate	3.25%
Expected stock price volatility	70%

The Company estimated the volatility of the ordinary shares of Plurinuva based on data from similar companies operating in the food tech field. The additional fair value determined was \$385.

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, 2022. The year-end balance sheet data was derived from the audited consolidated financial statements as of June 30, 2022, but not all disclosures required by U.S. GAAP are included.

Operating results for the three-month period ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending June 30, 2023.

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. 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, approximate their fair value because of their generally short-term maturities.

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;

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.)**

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.

e. 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 rules ("SRC")) to fiscal years beginning after December 15, 2022, including interim periods.

Early adoption is permitted. The Company meets the definition of an 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.

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 annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021.

The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

ASU 2021-04 -Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"):

In May 2021, the FASB issued ASU 2021-04 that provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. The Company has adopted ASU 2021-04, which has had an impact on the modification of the warrants to the non-controlling interest in Plurinuva. For further information also see note 1c.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**U.S. Dollars in thousands (except share and per share amounts)**

NOTE 3: - COMMITMENTS AND CONTINGENCIES

- a. As of September 30, 2022, an amount of \$1,287 of cash and deposits was pledged by the Subsidiary to secure its credit line for hedging transactions 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.

As of September 30, 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. 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 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.
- d. 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.
- e. As of September 30, 2022, total grants obtained under the “Shalav” program amounted to approximately \$52. As of September 30, 2022, the Company’s contingent liability with respect to royalties for this “Shalav” program was \$52 and no royalties were paid or accrued.

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, the German Subsidiary entered into a finance contract (the “Finance Contract”) with the EIB, pursuant to which the German Subsidiary can obtain a loan (the “Loan”) in the amount of up to €50 million, subject to certain milestones being reached, payable in three tranches, with the first tranche consisting of €20 million, second of €18 million and third of €12 million for a period of 36 months from the signing of the Finance Contract.

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

In addition to any interest payable on the Loan, the EIB is entitled to receive royalties from future revenues for a period of seven years starting at the beginning of fiscal year 2024 and continuing up to and including its fiscal year 2030 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.

During June 2021, Pluri received the first tranche in an amount of €20 million of the Finance Contract. 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 September 30, 2022, the linked principal balance in the amount of \$19,677 and the interest accrued in the amount of \$1,045 are presented among long-term liabilities.

The Finance Contract also contains certain limitations such as the use of proceeds received from the EIB, limitations related to disposal of assets, substantive changes in the nature of the Company’s business, changes in holding structure, distributions of future potential dividends and engaging with other banks and financing entities for other loans.

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 provided that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company could 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.

On September 21, 2022, as a result of General Instruction I.B.6 of Form S-3, and in accordance with the terms of the ATM Agreement, the Company reduced the amount available to be sold under the ATM Agreement to a maximum aggregate offering price of up to \$11,800 of its common shares from time to time through Jefferies.

During the three-month period ended September 30, 2022, the Company did not sell any common shares under the ATM Agreement.

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 equity incentive plans is as follows:

	Three months ended September 30, 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	91,045	\$ 1.32	7.05	\$ 44
Options outstanding at the end of the period	91,045	\$ 1.32	6.83	\$ 28
Options exercisable at the end of the period	47,295	\$ 0.53	6.70	\$ 28
Options unvested	43,750	\$ 2.18		
Options vested and expected to vest	91,045	\$ 1.32	6.83	\$ 28

Compensation expenses recorded in general and administration expenses related to options granted to consultants for the three months ended September 30, 2022 and 2021 were \$12 and \$2, 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 equity incentive plans for the three-month periods ended September 30, 2022 and 2021:

	Three months ended September 30,	
	2022	2021
	Number	
Unvested at the beginning of the period	1,935,014	2,404,415
Granted	-	40,000
Forfeited	(27,951)	(23,609)
Vested	(106,546)	(118,520)
Unvested at the end of the period	1,800,517	2,302,286
Expected to vest after the end of the period	1,770,417	2,261,117

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:

	Three months ended September 30,	
	2022	2021
Research and development expenses	\$ 63	\$ 209
General and administrative expenses	546	2,907
	<u>\$ 609</u>	<u>\$ 3,116</u>

Unamortized compensation expenses related to RSUs granted to employees and directors is approximately \$2,359 to be recognized by the end of June 2026.

2. RSUs to consultants:

The following table summarizes the activity related to unvested RSUs granted to consultants under the Company's equity incentive plans for the three-month periods ended September 30, 2022 and 2021:

	Three months ended September 30,	
	2022	2021
	Number	
Unvested at the beginning of the period	41,249	76,249
Vested	(20,625)	(20,625)
Unvested at the end of the period	<u>20,624</u>	<u>55,624</u>

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

	Three months ended September 30,	
	2022	2021
Research and development expenses	\$ 38	\$ 32
General and administrative expenses	(*)	38
	<u>\$ 38</u>	<u>\$ 70</u>

(*) Less than \$1

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. Dollars in thousands (except share and per share amounts)**NOTE 6: - SUBSEQUENT EVENT.**

On October 12, 2022, the Company received a letter (the “Notice”) from The Nasdaq Stock Market (“Nasdaq”) advising that for 30 consecutive trading days preceding the date of the Notice, the bid price of the Company’s common shares had closed below the \$1.00 per share minimum required for continued listing on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1), or the “Minimum Bid Price Requirement”(“MBPR”). The Notice has no effect on the listing of the Company’s common shares at this time, and the common shares continue to trade on Nasdaq under the symbol “PLUR.”

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice the closing bid price of the common shares is at or above \$1.00 for a minimum of 10 consecutive business days, the Company will regain compliance with the MBPR and the Company’s common shares will continue to be eligible for listing on Nasdaq, absent noncompliance with any other requirement for continued listing. The compliance period (“Compliance Period”) to comply with the MBPR will expire on April 10, 2023.

If the Company does not regain compliance with the MBPR by the end of the Compliance Period, then under Nasdaq Listing Rule 5810(c)(3)(A) (i), the Company may transfer to The Nasdaq Capital Market, provided that the Company meets the applicable market value of publicly held shares requirement for continued listing as well as all other standards for initial listing of the common shares on the Nasdaq Capital Market (other than the MBPR), and notifies Nasdaq of the Company’s intention to cure the deficiency. Following a transfer to The Nasdaq Capital Market, the Company may be afforded an additional 180-days to regain compliance with the MBPR.

The Company intends to monitor the closing bid price of its common shares and may, if appropriate, consider implementing available options to regain compliance with the MBPR under the Nasdaq Listing Rules, including initiating a reverse stock split.

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 regenerative medicine, biologics and food tech, as well as potentially in other industries and verticals that have a need for our mass scale and cost-effective cell expansion platform;
- 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 study plans, including timing of initiation, expansion, enrollment, results, and conclusion of trials;
- achieving regulatory approvals;
- 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 funds pursuant to our agreement with the European Investment Bank, or the EIB;
- developing capabilities for new clinical indications of placenta expanded, or PLX, cells and new products;
- the final results 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, 2022, or the 2022 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 “Pluri” mean Pluri Inc. and our wholly owned subsidiaries, Pluri Biotech 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 Good Manufacturing Practice, or 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.

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. 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.

Our operations are focused on the research, development and manufacturing of cells and cell-based products, conducting clinical studies and the business development of cell therapeutics and cell-based technologies, such as our 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 cultivated food platform and the recent collaboration agreement we signed with a leading European manufacturer of active pharmaceutical ingredients, or APIs, to use our expansion technology, which aims to revolutionize the production of biologics by enabling a cost-effective, sustainable and cruelty-free ingredient.

We expect to demonstrate a real-world impact and value from our cell-based technology platform, our current PLX pipeline and from other cell-based product candidates that may be developed based on our platform. Our business model for commercialization and revenue generation includes, but is not limited to, licensing deals, joint ventures, partnerships, joint development agreements and direct sale of our products.

In the pharmaceutical area, we are now completing a Phase III multinational clinical study in muscle recovery following surgery for hip fracture and we have completed 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 completed a Phase I clinical study for incomplete recovery following bone marrow transplantation in the United States and Israel, and our PLX cells are used in an investigator-led Phase I/II Chronic Graft versus Host Disease study in Israel. PLX R-18 product candidate is also being tested as a potential treatment for Acute Radiation Syndrome under the U.S. Food and Drug Administration animal rule. We believe that each of these indications is a severe unmet medical need.

Food Tech

On February 24, 2022, we announced the closing of the joint venture pursuant to joint venture agreement, or the Joint Venture Agreement, with Tnuva through the Subsidiary. Under the Joint Venture Agreement, we established a new company, Plurinuva, with the purpose of developing cultivated meat products of all types and kinds.

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, 187,500 ordinary shares, representing 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 \$7.5 million in cash.

The first warrant, or 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 month anniversary of the Closing Date, and provided that the First Warrant has not expired, Plurinuva shall issue to Tnuva a second warrant, or 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 \$2,500,000 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. On August 23, 2022, the First Warrant was extended for an additional 90-day period, so that the exercise period will end on November 22, 2022.

Technology Collaboration the Biologics Field

In September 2022 we entered into a collaboration agreement with a leading European manufacturer of APIs for liver and gastroenterological diseases. As part of our collaboration, our platform is being utilized to develop and manufacture a unique biologic API used in drugs that treat liver and gastroenterological diseases. The current source of this API is derived from animals that are sacrificed during the extraction process. The joint goal of the collaboration is to grow the specific cells needed for this API in our 3D cell expansion bioreactor systems that secrete the biological molecule without harming animals.

We believe that proof of concept with this agreement and APIs will open opportunities for us to serve additional API manufacturers in the rapidly growing biologics market.

RESULTS OF OPERATIONS – THREE MONTHS ENDED SEPTEMBER 30, 2022 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2021.

Revenues

Revenues for the three-month period ended September 30, 2022 were \$87,000, as compared to no revenues, during the three-month period ended September 30, 2021. Revenues for the three-month period ended September 30, 2022 were mainly related to our collaboration in the biologic field.

Research and Development Expenses, Net

Research and development, or R&D, expense, net (costs less participation and grants by the Horizon 2020 program, the IIA and other parties) for the three-month period ended September 30, 2022 decreased by 33% from \$6,353,000 for the three-month period ended September 30, 2021 to \$4,270,000. The decrease is mainly attributed to: (1) a decrease in clinical studies subcontractor expenses following the completion of our critical limb ischemia and ARDS associated with COVID-19 studies and the end of enrollment of our muscle regeneration following hip fracture study in November 2021 (2) a decrease in materials purchases in accordance with our manufacturing needs and plan, (3) a decrease in salaries and related expenses as part of our cost reduction, specifically a reduction of 26 R&D employees (110 on September 30, 2022, compared to 136 on September 30, 2021) and (4) a decrease in share-based compensation expenses.

General and Administrative Expenses

General and administrative expenses for the three-month period ended September 30, 2022 decreased by 46% from \$5,088,000 for the three-month period ended September 30, 2021 to \$2,740,000. The decrease is mainly attributed to a decrease in share-based compensation expenses related to market based vesting conditioned restricted stock units, or RSUs, granted to our CEO and Chairman, employee terminations and RSU expenses amortization over time.

Other Financial Income, net

Other financial income increased from \$237,000 for the three-month period ended September 30, 2021 to \$848,000 for the three-month period ended September 30, 2022. This increase is mainly attributable to income from exchange rate differences related to the EIB loan provided to us in June 2021 pursuant to the finance agreement executed with the EIB, or the EIB Finance Agreement, following the strength of the U.S. dollar against the Euro. This increase was partially offset by losses from hedging transactions linked to the Euro as a result of the strength of the U.S. dollar against the Euro and exchange rate expenses related to deposits linked to the NIS following the strength of the U.S. dollar against the NIS.

Interest Expenses

Interest expenses decreased from \$228,000 for the three-month period ended September 30, 2021 to interest expenses of \$194,000 for the three-month period ended September 30, 2022. This decrease is attributable only to exchange rate differences due to the strength of the U.S. dollar against the Euro.

Net Loss

Net loss for the three-month period ended September 30, 2022 was \$6,269,000, as compared to net loss of \$11,432,000 for the three-month periods ended September 30, 2021. The decrease was due to a decrease in general and administrative expenses and research and development expenses, as a result of our cost reduction plan and the implementation of our new business strategy. Net loss per share attributed to shareholders for the three-month period ended September 30, 2022 was \$0.19, as compared to \$0.36 for the three-month period ended September 30, 2021. We had net loss attributed to our non-controlling interest in Plurinuva for the three-month period ended September 30, 2022 of \$148,000.

For the three-month periods ended September 30, 2022 and 2021, we had weighted average common shares outstanding of 32,562,596, and 32,000,789, respectively, which were used in the computations of net loss per share for the three-month periods.

The increase in weighted average common shares outstanding reflects the issuances of additional shares upon the vesting of RSUs issued to directors, employees and consultants.

Liquidity and Capital Resources

As of September 30, 2022, our total current assets were \$49,723,000 and total current liabilities were \$5,018,000. On September 30, 2022, we had a working capital surplus of \$44,705,000, total equity of \$26,901,000, out of which \$2,709,000 is attributed to the non-controlling interest in Plurinuva, and an accumulated deficit of \$377,384,000.

Our cash and cash equivalents as of September 30, 2022 amounted to \$8,744,000, compared to \$14,611,000 as of September 30, 2021, and compared to \$9,772,000 as of June 30, 2022. Cash balances changed in the three months ended September 30, 2022 and 2021 for the reasons presented below.

Net cash used for operating activities was \$7,609,000 in the three months ended September 30, 2022, compared to \$8,789,000 in the three months ended September 30, 2021. The decrease is mainly attributed to a decrease in net loss following the completion of clinical trials and the implementation of our cost reduction and efficiency plan that we initiated in order to align with the change in our business strategy. Cash used in operating activities in the three months ended September 30, 2022 and 2021 consisted primarily of payments of fees to our suppliers, subcontractors, professional services providers and consultants, 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 \$6,393,000 in the three months ended September 30, 2022, compared to cash used of \$7,240,000 for the three months ended September 30, 2021. The investing activities in the three-month period ended September 30, 2022 consisted primarily of the withdrawal of \$6,466,000 of short-term deposits. The investing activities in the three-month period ended September 30, 2021, consisted primarily of the investment of \$12,084,000 in short-term deposits and proceeds of \$4,859,000 from withdrawal of long-term deposits.

No cash was used or provided from financing activities during the three months ended September 30, 2022, and 2021.

On July 16, 2020, we entered into an Open Market Sale AgreementSM, or the ATM Agreement with Jefferies LLC, or Jefferies, pursuant to which we were able to 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, net of issuance expenses of \$380,000.

On September 21, 2022, as a result of General Instruction I.B.6 of Form S-3, and in accordance with the terms of the Sales Agreement, we reduced the amount available to be sold under the ATM Agreement to a maximum aggregate offering price of up to \$11,800,000 of our common shares from time to time through Jefferies.

During the three month period ended September 30, 2022 we did not sell of our any common shares under the ATM Agreement.

In April 2020, we and our subsidiaries, Pluri 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. We do not expect to receive additional funds pursuant to the EIB Finance Agreement.

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 September 30, 2022, the interest accrued was in the amount of €1,063,000. 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 September, 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. The CRISPR-IL consortium program does not include any obligation to pay royalties.

Through September 30, 2022, we received total grants of approximately \$701,000 in cash from the IIA pursuant to the CRISPR-IL consortium program, out of which an amount of \$7,000 was received during the three-months ended September 30, 2022.

During the three-month period ended September 30, 2022, we received the final payment pursuant to the EU's Horizon 2020 PACE grant program in the amount of \$617,000.

On September 6, 2022, we announced that a €7.5 million non-dilutive grant from the European Union's Horizon program was awarded to PROTO (Advanced PeRsOnalized Therapies for Osteoarthritis), an international collaboration led by Charité Berlin Institute of Health Center for Regenerative Therapies. The goal of the PROTO project is to utilize our PLX-PAD cells in a Phase I/IIa study for the treatment of mild to moderate knee osteoarthritis. Final approval of the grant is subject to completion of the consortium and Horizon Europe grant agreements. The funds from the grant are expected to be allocated between Pluri and other members of the consortium in accordance with budget and work packages which will be determined by the consortium.

The Phase I/II study will be carried out by Charité, together with us and other members of the international consortium under the leadership of Professor Tobias Winkler, Principal Investigator, at the Berlin Institute of Health Center of Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery.

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 November 8, 2022, other than the \$11,800,000 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 \$377,384,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. 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 technology and maintain our research and development and clinical study activities.

We are continually looking for sources of funding, including non-diluting sources such as collaboration with other companies via licensing agreements, the IIA grants, the European Union grant and other research grants, and sales of our common shares.

We believe that we have sufficient cash to fund our operations for at least the next twelve 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 first quarter of fiscal year 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 1A. Risk Factors.

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 2022 Annual Report, which could materially affect our business, financial condition or future results.

We could fail to maintain the listing of our common shares on Nasdaq, which could harm the liquidity of our shares and our ability to raise capital or complete a strategic transaction.

On October 12, 2022, we received a letter, or Notice, from The Nasdaq Stock Market, or Nasdaq, advising us that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common shares had closed below the \$1.00 per share minimum required for continued listing on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) the "Minimum Bid Price Requirement", or MBPR. The Notice has no effect on the listing of our common shares at this time, and our common shares continue to trade on Nasdaq under the symbol "PLUR."

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice the closing bid price of our common shares is at or above \$1.00 for a minimum of 10 consecutive business days, we will regain compliance with the MBPR and our common shares will continue to be eligible for listing on Nasdaq, absent noncompliance with any other requirement for continued listing. The compliance period, or Compliance Period, to comply with the MBPR will expire on April 10, 2023.

If we do not regain compliance with the MBPR by the end of the Compliance Period, then under Nasdaq Listing Rule 5810(c)(3)(A)(i) we may transfer to The Nasdaq Capital Market, provided that we meet the applicable market value of publicly held shares requirement for continued listing as well as all other standards for initial listing of our common shares on the Nasdaq Capital Market (other than the MBPR) and notify Nasdaq of our intention to cure the deficiency. Following a transfer to The Nasdaq Capital Market, we may be afforded an additional 180-days to regain compliance with the MBPR.

As of the date of this filing, our common shares are trading below \$1.00 per share. If we do not regain compliance with the MBPR by the end of the Compliance Period (or the Compliance Period as may be extended) our common shares will be subject to delisting. A delisting from Nasdaq would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on shareholders:

- the liquidity of our common shares;
- the market price of our common shares;
- the availability of information concerning the trading prices and volume of our common shares;
- our ability to obtain financing or complete a strategic transaction;
- the number of institutional and other investors that will consider investing in our common shares; and
- the number of market makers or broker-dealers for our common shares.

We intend to monitor the closing bid price of our common shares and may, if appropriate, consider implementing available options to regain compliance with the MBPR under the Nasdaq Listing Rules, including initiating a reverse stock split.

PART II—OTHER INFORMATION

Item 6. Exhibits.

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 September 30, 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 (vi) 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.

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.

PLURI INC.

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

Date: November 10, 2022

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

Date: November 10, 2022

CERTIFICATION

I, Yaky Yanay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluri Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of 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(s) 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(s) 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.

Date: November 10, 2022

/s/ Yaky Yanay

Yaky Yanay

Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATION

I, Chen Franco-Yehuda, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluri Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of 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(s) 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(s) 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.

Date: November 10, 2022

/s/ Chen Franco-Yehuda

Chen Franco-Yehuda
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report on Form 10-Q of Pluri Inc., or the Company, for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Yaky Yanay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

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

Dated: November 10, 2022

/s/ Yaky Yanay

Yaky Yanay

Chief Executive Officer and President

(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report on Form 10-Q of Pluri Inc., or the Company, for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Chen Franco-Yehuda, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

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

Dated: November 10, 2022

/s/ Chen Franco-Yehuda

Chen Franco-Yehuda
Chief Financial Officer
(Principal Financial and Accounting Officer)