

---

**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, 2017**

☐ 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 31905**

(Address of principal executive offices)

---

**011-972-74-7108607**

(Registrant's telephone number)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated 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 ☐ (do not check if a smaller reporting company)

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 stock as of the latest practicable date: 108,111,908 shares of common stock issued and outstanding as of November 2, 2017.

---

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

As of September 30, 2017

(Unaudited)

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

As of September 30, 2017

U.S. DOLLARS IN THOUSANDS

(Unaudited)

INDEX

	<u>Page</u>
<a href="#">Interim Condensed Consolidated Balance Sheets</a>	F - 2- F - 3
<a href="#">Interim Condensed Consolidated Statements of Operations</a>	F - 4
<a href="#">Interim Condensed Consolidated Statements of Comprehensive Loss</a>	F - 5
<a href="#">Interim Condensed Statements of Changes in Stockholders' Equity</a>	F - 6 - F - 7
<a href="#">Interim Condensed Consolidated Statements of Cash Flows</a>	F - 8 - F - 9
<a href="#">Notes to Interim Condensed Consolidated Financial Statements</a>	F - 10 - F - 21

---

## INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	September 30, 2017 Unaudited	June 30, 2017
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents		\$ 12,294	\$ 4,707
Short-term bank deposits		2,151	6,235
Restricted cash and short-term bank deposits		599	559
Marketable securities	3	6,301	15,164
Accounts receivable from the Israeli Innovation Authority ("IIA")		25	1,036
Other current assets		1,471	1,315
<b>Total current assets</b>		<b>22,841</b>	<b>29,016</b>
<b>LONG-TERM ASSETS:</b>			
Long-term deposits and restricted bank deposits		397	403
Severance pay fund		817	804
Property and equipment, net		6,851	7,277
Other long-term assets		48	34
<b>Total long-term assets</b>		<b>8,113</b>	<b>8,518</b>
<b>Total assets</b>		<b>\$ 30,954</b>	<b>\$ 37,534</b>

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

## INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Note	September 30, 2017 Unaudited	June 30, 2017
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
Trade payables		\$ 1,553	\$ 1,966
Accrued expenses		1,486	1,465
Other accounts payable		1,732	1,983
<b>Total current liabilities</b>		<b>4,771</b>	<b>5,414</b>
<b>LONG-TERM LIABILITIES</b>			
Accrued severance pay		950	940
Other long-term liabilities		869	929
<b>Total long-term liabilities</b>		<b>1,819</b>	<b>1,869</b>
<b>COMMITMENTS AND CONTINGENCIES</b>	5		
<b>STOCKHOLDERS' EQUITY</b>			
Share capital:	6		
Common stock \$0.00001 par value per share:			
Authorized: 200,000,000 shares			
Issued and outstanding: 98,183,725 shares as of			
September 30, 2017, 96,938,789 shares as of June 30, 2017		1	1
Additional paid-in capital		220,375	217,822
Accumulated deficit		(196,956)	(189,571)
Other comprehensive income		944	1,999
<b>Total stockholders' equity</b>		<b>24,364</b>	<b>30,251</b>
<b>Total liabilities and stockholders' equity</b>		<b>\$ 30,954</b>	<b>\$ 37,534</b>

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

**INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

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

	<b>Three months ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
Research and development expenses	\$ (5,192)	\$ (6,031)
Less: participation by the IIA and other parties	515	1,033
Research and development expenses, net	(4,677)	(4,998)
General and administrative expenses, net	(2,763)	(1,564)
Operating loss	(7,440)	(6,562)
Financial income, net	55	238
Net loss	<u>\$ (7,385)</u>	<u>\$ (6,324)</u>
Loss per share:		
Basic and diluted net loss per share	<u>\$ (0.08)</u>	<u>\$ (0.08)</u>
Weighted average number of shares used in computing basic and diluted net loss per share	<u>97,321,866</u>	<u>80,674,961</u>

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

**INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)****U.S. Dollars in thousands**

	<b>Three months ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
Net loss	\$ (7,385)	\$ (6,324)
Other comprehensive income (loss), net:		
Unrealized gain (loss) on available-for-sale marketable securities, net	(1,133)	586
Reclassification adjustment of available-for-sale marketable securities for gains (losses) realized included in net loss	78	(4)
Other comprehensive income (loss)	(1,055)	582
Total comprehensive loss	<u>\$ (8,440)</u>	<u>\$ (5,742)</u>

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

## INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount	Capital	Income (Loss)	Deficit	Stockholders' Equity
Balance as of July 1, 2016	80,268,999	\$ 1	\$ 198,432	\$ 1,480	\$ (161,757)	\$ 38,156
Exercise of options by employees	6,000	(*)	4	-	-	4
Stock-based compensation to employees, directors and non-employee consultants	505,202	(*)	485	-	-	485
Other comprehensive income, net	-	-	-	582	-	582
Net loss	-	-	-	-	(6,324)	(6,324)
Balance as of September 30, 2016 (unaudited)	80,780,201	\$ 1	\$ 198,921	\$ 2,062	\$ (168,081)	\$ 32,903

(\*) Less than \$1

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



## INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of July 1, 2017</b>	96,938,789	\$ 1	\$ 217,822	\$ 1,999	\$ (189,571)	\$ 30,251
Stock-based compensation to employees, directors and non-employee consultants	394,096	(*)	1,503	-	-	1,503
Issuance of common stock under At-The Market ("ATM") Agreement, net of issuance costs of \$80 (see Note 6a)	834,040	(*)	1,026	-	-	1,026
Exercise of warrants by investors	16,800	(*)	24	-	-	24
Other comprehensive loss, net	-	-	-	(1,055)	-	(1,055)
Net loss	-	-	-	-	(7,385)	(7,385)
<b>Balance as of September 30, 2017 (unaudited)</b>	<u>98,183,725</u>	<u>\$ 1</u>	<u>\$ 220,375</u>	<u>\$ 944</u>	<u>\$ (196,956)</u>	<u>\$ 24,364</u>

(\*) Less than \$1

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

## INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Three months ended September 30,	
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (7,385)	\$ (6,324)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	515	558
Gain from sale of property and equipment, net	-	(4)
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	13	(33)
Gain from sale of investments of available-for-sale marketable securities	(928)	(4)
Other-than-temporary loss of available-for-sale marketable securities	850	-
Stock-based compensation to employees, directors and non-employees consultants	1,503	485
Decrease in accounts receivable from the IIA	1,011	1,769
Decrease (increase) in other current assets and other long-term assets	(170)	68
Decrease in trade payables	(354)	(389)
Decrease in other accounts payable, accrued expenses, other current liabilities and other long-term liabilities	(290)	(44)
Decrease (increase) in interest receivable on short-term deposits	45	(2)
Linkage differences and interest on short and long-term deposits and restricted bank deposits	3	(3)
Accrued severance pay, net	(3)	-
Net cash used by operating activities	\$ (5,190)	\$ (3,923)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$ (148)	\$ (145)
Proceeds from sale of property and equipment	-	6
Repayment of short-term deposits	4,002	1,834
Investment in long-term deposits and restricted bank deposits	-	(2)
Proceeds from sale of available-for-sale marketable securities	9,010	2,732
Proceeds from redemption of available-for-sale marketable securities	9	55
Investment in available-for-sale marketable securities	(1,146)	(686)
Net cash used in investing activities	\$ 11,727	\$ 3,794

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

## INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Three months ended September 30,	
	2017	2016
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Exercise of warrants and options	\$ 24	4
Proceeds related to issuance of common stock, net of issuance costs	1,026	-
Net cash provided by financing activities	\$ 1,050	\$ 4
Increase (decrease) in cash and cash equivalents	7,587	(125)
Cash and cash equivalents at the beginning of the period	4,707	6,223
Cash and cash equivalents at the end of the period	\$ 12,294	\$ 6,098
<b>(a) Supplemental disclosure of cash flow activities:</b>		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$ 3	\$ 8
<b>(b) Supplemental disclosure of non-cash activities:</b>		
Purchase of property and equipment on credit	\$ 29	\$ 98

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

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 1:-GENERAL**

- a. Pluristem Therapeutics Inc., a Nevada corporation, was incorporated on May 11, 2001. Pluristem Therapeutics Inc. has a wholly owned subsidiary, Pluristem Ltd. (the "Subsidiary"), which is incorporated under the laws of the State of Israel. Pluristem Therapeutics Inc. and the Subsidiary are referred to as the "Company" or "Pluristem".

The Company's shares of common stock are traded on the NASDAQ Capital Market under the symbol "PSTI" and on the Tel-Aviv Stock Exchange under the symbol "PLTR".

- b. The Company is a bio-therapeutics company developing placenta-based cell therapy product candidates for the treatment of multiple ischemic and inflammatory conditions. The Company has incurred an accumulated deficit of approximately \$196,956 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of September 30, 2017, the Company's total stockholders' equity amounted to \$24,364.

During the three month period ended September 30, 2017, the Company incurred operating losses of \$7,440 and its negative cash flow from operating activities was \$5,190. The Company will be required to identify additional liquidity resources in the near term in order to support the commercialization of its products and maintain its research and development and clinical trials activities.

As of September 30, 2017, the Company's cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$20,746. The Company is addressing its liquidity issues by implementing initiatives to allow the continuation of its activities. The Company's current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures. The Company's ability to successfully carry out its business plan, which includes a cost-reduction plan should it be unable to raise sufficient additional capital, is primarily dependent upon its ability to (1) obtain sufficient additional capital, (2) enter into license agreements to use or commercialize the Company's products and (3) receive other sources of funding, including non-diluting sources such as the IIA grants, the European Union's Horizon 2020 program ("Horizon 2020") grants and other grants. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its products.

According to management estimates, liquidity resources as of September 30, 2017, together with the funds received from the public offering that closed on October 31, 2017, (see Note 7a) will be sufficient to maintain the Company's operations into the third quarter of the Company's fiscal year 2019. The Company's inability to raise funds to carry out its business plan will have a severe negative impact on its ability to remain a viable company.

- c. License Agreements:

**CHA Biotech Co. Ltd. ("CHA") Agreement**

On June 26, 2013, Pluristem entered into an exclusive license and commercialization agreement (the "CHA Agreement") with CHA, for conducting clinical trials and commercialization of Pluristem's PLX-PAD product in South Korea in connection with two indications: the treatment of Critical Limb Ischemia ("CLI"), and Intermediate Claudication (collectively with CLI, the "Indications"). Under the terms of the CHA Agreement, CHA will receive exclusive rights in South Korea for conducting clinical trials with respect to the Indications and the Company will continue to retain rights to its proprietary manufacturing technology and cell-related intellectual property.

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

---

**NOTE 1-GENERAL (CONT.)**

The first clinical study as part of the CHA Agreement is a Phase II trial in Intermittent Claudication. South Korea's Ministry of Food and Drug Safety approved this study in November 2013.

Upon the first regulatory approval for a PLX product in South Korea, for the specified indications, Pluristem and CHA will establish an equally owned joint venture. The purpose of the joint venture will be to commercialize PLX cell products in South Korea.

Pluristem will be able to use the data generated by CHA to pursue the development of PLX product candidates outside of South Korea.

The CHA Agreement contains customary termination provisions, including in the event the parties do not reach an agreement upon development plan for conducting the clinical trials. Upon termination of the CHA Agreement, the license granted thereunder will terminate and all rights included therein will revert to the Company, and the Company will be free to enter into agreements with any other third parties for the granting of a license in or outside South Korea or to deal in any other manner with such rights as it shall see fit at its sole discretion.

In addition, and as contemplated by the CHA Agreement, in December 2013, Pluristem and CHA executed the mutual investment pursuant to which Pluristem issued 2,500,000 shares of its common stock in consideration for 1,011,504 shares of CHA, which reflects total consideration to each of Pluristem and CHA of approximately \$10,414. The parties also agreed to give an irrevocable proxy to the other party's management with respect to the voting power of the shares issued.

During March 2015, the Company sold a portion of the CHA shares received in December 2013.

The remaining investment in CHA shares is presented as "Marketable Securities" and classified as available-for-sale in accordance with Accounting Standards Codification ("ASC") 320, "Investments - Debt and Equity Securities". The fair value of the remaining investment in CHA's shares as of September 30, 2017, is approximately \$4,093.

**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 presentation have been included (consisting only of normal recurring adjustments except as otherwise discussed).

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, 2017.

Operating results for the three month periods ended September 30, 2017, are not necessarily indicative of the results that may be expected for the year ending June 30, 2018.

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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 and other liabilities, approximate fair value because of their generally short term maturities.

The Company measures its investments in marketable securities and derivative instruments at fair value under ASC 820, "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 (see Note 4).

e. *Derivative financial instruments*

The Company accounts for derivatives and hedging based on ASC 815, "Derivatives and hedging" ("ASC 815"), as amended and related interpretations. ASC 815 requires the Company to recognize all derivatives on the balance sheet at fair value. If a derivative meets the definition of a hedge and is so designated, depending on the nature of the hedge, changes in the fair value of the derivative will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings (for fair value hedge transactions) or recognized in other comprehensive income (loss) until the hedged item is recognized in earnings (for cash flow hedge transactions).

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The ineffective portion of a derivative's change in fair value is recognized in earnings. If a derivative does not meet the definition of a hedge, the changes in the fair value are included in earnings. Cash flows related to such hedges are classified as operating activities. The Company enters into forward exchange contracts and option contracts in order to limit the exposure to exchange rate fluctuation associated with expenses mainly incurred in New Israeli Shekels ("NIS"). Since the derivative instruments that the Company holds do not meet the definition of hedging instruments under ASC 815, any gain or loss derived from such instruments is recognized immediately as "financial income, net".

The Company measured the fair value of the contracts in accordance with ASC 820. Foreign currency derivative contracts are classified within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments. As of September 30, 2017 the fair value of the options contracts was approximately\$ 152, presented in "other current assets" (see Note 4). The net gains (losses) recognized in "Financial income, net" during the three month periods ended September 30, 2017 and 2016, were (\$143) and \$65, respectively.

f. *Recent Accounting Pronouncement*Accounting Standards Update ("ASU") 2014-09 – "Revenue from Contracts with Customers (Topic 606)":

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09 (Topic 606) "Revenue from Contracts with Customers" ("Topic 606"). Topic 606 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition", and requires entities to recognize revenue when they transfer control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company was an early adopter of Topic 606 as of July 1, 2017, using the modified retrospective transition method. Prior periods were not retrospectively adjusted. As the Company currently does not have any contracts with customers which are not completed as of the adoption date, the adoption of Topic 606 does not have a material impact on the Company's consolidated financial statements and related disclosures.

ASU 2017-11 - Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features. (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU No. 2017-11"):

In July 2017, the FASB issued ASU No. 2017-11. The ASU was issued to address the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. The ASU, among other things, eliminates the need to consider the effects of down round features when analyzing convertible debt, warrants and other financing instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The Company was an early adopter of ASU 2017-11 as of July 1, 2017. The adoption of ASU 2017-11 does not have a material impact on the Company's consolidated financial statements and related disclosures.

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (CONT.)**ASU 2016-02 - Leases (Topic 842):

In February 2016, the FASB issued guidance on the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a manner similar to the accounting under existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. Topic 842 supersedes the previous leases standard, ASC 840, "Leases". The guidance is effective for the interim and annual periods beginning on or after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the potential effect of the guidance on its consolidated financial statements.



## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 3:- MARKETABLE SECURITIES

As of September 30, 2017, all of the Company's marketable securities were classified as available-for-sale.

	September 30, 2017					June 30, 2017				
	Amortized cost	Gross unrealized gain	Gross unrealized loss	Other- than- temporary impairment	Fair value	Amortized cost	Gross unrealized gain	Gross unrealized loss	Other- than- temporary impairment	Fair value
<b>Available-for-sale - matures within one year:</b>										
Stock and index linked notes	\$ 6,207	\$ 1,209	\$ (265)	\$ (850)	\$ 6,301	\$ 11,988	\$ 2,014	\$ (47)	\$ (767)	\$ 13,188
Government debentures – fixed interest rate	-	-	-	-	-	157	1	-	-	158
Corporate debentures – fixed interest rate	-	-	-	-	-	47	1	-	-	48
	\$ 6,207	\$ 1,209	\$ (265)	\$ (850)	\$ 6,301	\$ 12,192	\$ 2,016	\$ (47)	\$ (767)	\$ 13,394
<b>Available-for-sale - matures after one year through five years:</b>										
Government debentures – fixed interest rate	-	-	-	-	-	468	23	-	-	491
Corporate debentures – fixed interest rate	-	-	-	-	-	1,255	7	(1)	-	1,261
	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,723	\$ 30	\$ (1)	\$ -	\$ 1,752
<b>Available-for-sale - matures after five years through ten years:</b>										
Corporate debentures – fixed interest rate	-	-	-	-	-	17	1	-	-	18
	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 17	\$ 1	\$ -	\$ -	\$ 18
<b>Total</b>	<u>\$ 6,207</u>	<u>\$ 1,209</u>	<u>\$ (265)</u>	<u>\$ (850)</u>	<u>\$ 6,301</u>	<u>\$ 13,932</u>	<u>\$ 2,047</u>	<u>\$ (48)</u>	<u>\$ (767)</u>	<u>\$ 15,164</u>

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 3:- MARKETABLE SECURITIES (CONT.)**

The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of September 30, 2017 and June 30, 2017, and the length of time that those investments have been in a continuous loss position:

	Less than 12 months		12 months or greater	
	Fair Value	Gross unrealized loss	Fair Value	Gross unrealized loss
As of September 30, 2017 (Unaudited)	\$ 4,093	\$ (265)	\$ -	\$ -
As of June 30, 2017	\$ 869	\$ (24)	\$ 106	\$ (24)

The Company typically invests in highly-rated securities. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis.

Based on the above factors, the Company concluded that unrealized losses in the amount of \$265 on all available-for-sale securities were not other-than-temporary and no credit loss was present for any of its investments. As such, the Company recognized other-than-temporary impairment losses on outstanding securities during the three month period ended September 30, 2017 of \$850.

**NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS**

	September 30, 2017 (Unaudited)		June 30, 2017	
	Level 1	Level 2	Level 1	Level 2
Marketable securities	\$ 4,093	\$ 2,208	\$ 10,523	\$ 4,641
Foreign currency derivative instruments	-	152	-	295
Total financial assets	\$ 4,093	\$ 2,360	\$ 10,523	\$ 4,936

**NOTE 5:- COMMITMENTS AND CONTINGENCIES**

- a. An amount of \$996 of cash and deposits was pledged by the Subsidiary to secure the derivatives and hedging transactions, credit line and bank guarantees as of September 30, 2017.
- 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.

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 5: - COMMITMENTS AND CONTINGENCIES (CONT.)**

Regulations under the Research Law generally provide for the payment of royalties to the IIA of 3%-4% 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 September 30, 2017, total grants obtained aggregated to approximately \$25,818 and total royalties paid and accrued amounted to \$166. As of September 30, 2017, the Company's contingent liability in respect to royalties to the IIA amounted to \$25,652, not including LIBOR interest as described above.

- c. In July 2017, the Company was awarded an additional "Smart Money" grant of approximately \$229 from Israel's Ministry of Economy and Industry to help penetrate the Chinese market, including Hong Kong, with its advanced cell therapy products. 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 for 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 for a period of up to 5 years or until the amount of the grant is fully paid.

Through September 30, 2017, no royalties were paid or accrued.

- d. 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 ("GvHD").

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 GvHD, with a maximum aggregate royalty amount of approximately \$250.

**NOTE 6: - STOCKHOLDERS' EQUITY**

- a. Pursuant to a shelf registration on Form S-3 declared effective by the Securities and Exchange Commission on June 23, 2017, in July 2017 the Company entered into an At Market Issuance Sales Agreement ("ATM Agreement") with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc. (collectively, the "Agents"), 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 shares of common stock having an aggregate offering price of up to \$80,000 through the Agents acting as sales agent. During the three month period ended September 30, 2017, the Company had issued 834,040 shares of common stock at an average price of \$1.33 per share. The company raised approximately \$1,026, net of issuance expenses of \$80, under the ATM agreement.

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

## b. Options, warrants, restricted stocks ("RS") and restricted stock units ("RSU") to employees, directors and consultants:

## 1. Options to employees and directors:

The Company accounts for its options to employees and directors under the fair value method in accordance with ASC 718, "Compensation—Stock Compensation". A summary of the Company's activity for options granted to employees and directors under its 2005 incentive option plan is as follows:

Three months ended September 30, 2017 (Unaudited)				
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	815,650	\$ 2.98		
Options forfeited	(71,400)	\$ 6.17		
Options outstanding at end of the period	744,250	\$ 2.665	0.645	\$ 315
Options exercisable at the end of the period	744,250	\$ 2.665	0.645	\$ 315
Options vested	744,250	\$ 2.665	0.645	\$ 315

Intrinsic value of exercisable options (the difference between the Company's closing stock price on the last trading day in the period and the exercise price, multiplied by the number of in-the-money options) represents the amount that would have been received by the employees and directors option holders had all option holders exercised their options on September 30, 2017. This amount changes based on the fair market value of the Company's common stock.

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

## b. Options, warrants, restricted stocks and restricted stock units to employees, directors and consultants (cont.):

## 2. Options to non-employees:

A summary of the options to non-employee consultants is as follows:

Three months ended September 30, 2017 (Unaudited)				
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	177,200	\$ 0.72		
Options outstanding at end of the period	177,200	\$ 0.72	4.05	\$ 229
Options exercisable at the end of the period	176,750	\$ 0.73	4.03	\$ 211
Options vested and expected to vest	177,200	\$ 0.72	4.05	\$ 229

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

Three months ended September 30,			
	2017	2016	
	(Unaudited)		
Research and development expenses	\$ 3	\$ -	
General and administrative expenses	\$ 15	\$ -	
	\$ 18	\$ -	

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

## b. Options, warrants, restricted stock and restricted stock units to employees, directors and consultants (cont.):

## 3. RS and RSUs to employees and directors:

The following table summarizes the activity related to unvested RS and RSUs granted to employees and directors under its 2005 and 2016 incentive option plan for the three month period ended September 30, 2017, (Unaudited) is as follows:

	<u>Number</u>
Unvested at the beginning of period	6,064,901
Granted	9,000
Forfeited	(61,858)
Vested	(374,096)
Unvested at the end of the period	<u>5,637,947</u>
Expected to vest after September 30, 2017	<u>5,568,796</u>

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

	<u>Three months ended</u> <u>September 30,</u>	
	<u>2017</u>	<u>2016</u>
	<u>(Unaudited)</u>	
Research and development expenses	\$ 144	\$ 110
General and administrative expenses	1,290	262
	<u>\$ 1,434</u>	<u>\$ 372</u>

Unamortized compensation expenses related to RSUs granted to employees and directors to be recognized over an average time of approximately 3.75 years are approximately \$5,364.

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

## b. Options, warrants, restricted stock and restricted stock units to employees, directors and consultants (cont.):

## 4. RS and RSUs to consultants:

The following table summarizes the activity related to unvested RS and RSUs granted to consultants for the three months ended September 30, 2017 (Unaudited):

	Number
Unvested at the beginning of period	42,500
Granted	24,580
Vested	(20,000)
Unvested at the end of the period	47,080

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

	Three months ended September 30,	
	2017	2016
	(Unaudited)	
Research and development expenses	\$ -	\$ 4
General and administrative expenses	51	109
	\$ 51	\$ 113

## NOTE 7:-SUBSEQUENT EVENTS

- a. On October 31, 2017, the Company completed a public offering in Israel, pursuant to the Company's existing shelf in the United States and a shelf registration statement filed in Israel, pursuant to which the Company raised aggregate gross proceeds of \$15,051 through the sale of 9,000,000 shares of the Company's common stock at a purchase price of \$1.67 per share. The net proceeds, after deducting fees and estimated expenses were approximately \$13,674.
- b. On October 2, 2017, the nTRACK, a collaborative project carried out by an international consortium led by LEITAT a technological Institute with the mission of collaborating with companies and other entities to create economic, social and sustainable value by research and development projects and technology processes from innovation and creativity, was awarded a Euro 6,800 (approximately \$8,000) non-royalty bearing grant. An amount of Euro 500 (approximately \$600) is a direct grant allocated to the Company. The Company also expects to benefit from cost savings resulting from grant amounts allocated to the other consortium members. Final approval of the grant is subject to the finalization of the consortium and Horizon 2020 grant agreements.

## 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;

the clinical trials to be conducted according to our license agreement with CHA Biotech Co. Ltd.;

our plan to execute our strategy independently, using our own personnel, and through relationships with research and clinical institutions or in collaboration with other companies;

the prospects of entering into additional license agreements, or other forms of cooperation with other companies and medical institutions;

our pre-clinical and clinical trials plans, including timing of initiation, enrollment and conclusion of trials;

achieving regulatory approvals, including under accelerated paths;

receipt of future funding from the Israel Innovation Authority, or IIA;

our marketing plans, including timing of marketing our first product, PLX-PAD;

developing capabilities for new clinical indications of placenta expanded (PLX) cells and new products;

our estimations regarding the size of the global market for our product candidates;

our expectations regarding our production capacity;

our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;

our expectations regarding our short- and long-term capital requirements;

the proposed joint venture, described in the overview below, to be established with Sosei Corporate Venture Capital Ltd. for the clinical development and commercialization of Pluristem's PLX-PAD cell therapy product in Japan, the plan to enter into definitive agreements and the timing of entering into such agreements;

our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses; and

information with respect to any other plans and strategies for our business.



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, 2016, or the 2016 Annual 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, the terms "we", "us", "our", the "Company" and "Pluristem" mean Pluristem Therapeutics Inc. and our wholly owned subsidiary, Pluristem Ltd., unless otherwise indicated or as otherwise required by the context.

## Overview

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. Our lead indications are critical limb ischemia, or CLI, recovery after surgery for femoral neck fracture, and acute radiation syndrome, or ARS. A pivotal, multinational clinical trial is currently being conducted with our PLX-PAD product candidate in CLI. In addition, pivotal, multinational clinical trials are planned for our PLX-PAD product candidate in femoral neck fractures. The National Institutes of Health's National Institute of Allergy and Infectious Diseases, or NIAID, recently completed a dose selection trial with PLX-R18 in the hematologic component of ARS and a pivotal study is planned under the U.S. Food and Drug Administration, or FDA, animal rule once funding will be secured for this project. Each of these indications is a severe unmet medical need.

PLX cells are derived from a class of placental cells that are harvested from donated placentas at the time of full term healthy delivery of a baby. PLX cell products require no tissue matching prior to administration. They are produced using our proprietary three-dimensional expansion technology. Our manufacturing facility complies with the FDA's current Good Manufacturing Practice requirements and has been approved by the European, Japanese and Israeli regulatory authorities for production of PLX-PAD for late stage trials and marketing. We expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

Our goal is to make significant progress with our robust clinical pipeline and our anticipated pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We intend to shorten the time to commercialization of our product candidates, by leveraging unique accelerated regulatory pathways that exist in the United States, Europe and Japan to bring innovative products that address life-threatening diseases to the market efficiently. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole. We are pursuing these accelerated pathways for PLX-PAD in CLI and femoral neck fracture. Our second product candidate, PLX R18, is under development in the United States for ARS via the Animal Rule regulatory pathway, which may result in approval without the prior performance of human efficacy trials. We expect to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity.

In May 2015, we announced that the PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines Agency, or EMA. During fiscal year 2017, the FDA, the United Kingdom's Medicines & Healthcare Products Regulatory Agency, the Paul Ehrlich Institute and the Austrian Agency for Health and Food Safety, each cleared our application to begin the pivotal Phase III trial of PLX-PAD cells in the treatment of CLI for patients who are unsuitable for revascularization in the United States, the United Kingdom, Germany and Austria. This multinational Phase III trial is being conducted in the United States and Europe.

Our intention is to file a request for marketing authorization in the United States and in Europe following a successful completion of this 250-patient (estimated) trial. An interim efficacy analysis is planned to be conducted based on data from the first 125 patients. If these trials yield positive results, they could lead to early conditional marketing approval in Europe.

In September 18, 2017, we announced that the FDA has granted a fast track designation to our ongoing Phase III study of PLX-PAD cells for the treatment of CLI in patients ineligible for revascularization. The FDA's fast track designation is a process designed to facilitate the development and expedite the review of drug to treat serious conditions and unmet medical needs. With fast track designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

In August 2016, our CLI program in the European Union was awarded a Euro 7,600,000 (approximately \$9,000,000) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD in CLI will be a collaborative project carried out by an international consortium led by the Berlin-Brandenburg Center for Regenerative Therapies together with us and with participation of additional third parties. The grant will cover a significant portion of the CLI program costs. An amount of Euro 1,900,000 (approximately \$2,200,000) is a direct grant allocated to us for manufacturing and other costs, and we also expect to have direct benefit from cost savings resulting from grant amounts allocated to the other consortium members. In July 2017, the consortium amended the consortium agreement, pursuant to which the original grant allocation has been amended such that we will receive an additional direct grant of Euro 1,000 (approximately \$1,200). The additional direct grant was allocated to us from the total amount of the original grant.

In December 2016, we announced that we signed a binding term sheet with Sosei Corporate Venture Capital Ltd., or Sosei CVC, for the establishment of a new Japanese corporation, or NewCo, for the clinical development and commercialization of our PLX-PAD cell therapy product in Japan for CLI. The parties plan to establish NewCo in Japan, in which we will own 35% of the equity in return for our contribution of a perpetual license to commercialize PLX-PAD for CLI in Japan. All proprietary rights related to PLX-PAD will be exclusively owned by us. Sosei CVC's investment fund, Sosei RMF1, together with additional Japanese investors, will raise and invest approximately \$11 million, equivalent to approximately ¥1.3 billion, in return for ownership of 65% of NewCo. The parties have agreed to extend the deadline to enter into a definitive agreement until December 31, 2017. In December 2015, we reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of CLI. The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine.

In July 2016, we announced our intent to conduct a Phase III trial assessing our PLX-PAD cells in recovery following surgery for femoral neck fracture in the United States and Europe. In addition, the EMA, confirmed that this indication would also be eligible for the Adaptive Pathways project.

In September 2017, our Phase III study of PLX-PAD cells to support recovery following surgery for femoral neck fracture was awarded a Euro 7,400,000 (approximately \$8,700,000) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD to support recovery following surgery for femoral neck fractures will be a collaborative project carried out by an international consortium led by Charite Universitätsmedizin Berlin, together with us, and with participation of additional third parties. The grant will cover a significant portion of the project costs. An amount of Euro 2,400,000 (approximately \$2,800,000) is a direct grant allocated to us for manufacturing and other costs, and we also expect to have a direct benefit from cost savings resulting from grant amounts allocated to the other consortium members.

In May 2017, we announced promising results of our non-human primates, or NHPs, pilot study for PLX-R18 as a treatment for ARS. The study, conducted and funded by the NIAID, was designed to assess the safety and efficacy of PLX-R18 following intramuscular injection into irradiated and non-irradiated NHPs. Efficacy measures included survival as well as level of bone marrow function, which is affected by exposure to high levels of radiation as may occur in a nuclear accident or attack. These data will help support a pivotal study designed to meet the requirements for a Biologics License Application submission under the FDA's Animal Rule regulatory pathway.

In December 2015, we also signed a Memorandum of Understanding for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop our PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients. In August 2017, we announced that a pilot study of our PLX-R18 cell therapy will be initiated by the U.S. Department of Defense's Armed Forces Radiobiology Research Institute, part of the Uniformed Services University of Health Sciences. The study will examine the effectiveness of PLX-R18 as a treatment for ARS prior to, and within the first 24 hours of exposure to radiation.

In October 2017, we announced that the FDA has granted the company an orphan drug designation for its PLX-R18 cell therapy for the prevention and treatment of ARS.

In January 2017, we announced that we had completed enrollment of all 172 patients in the randomized, double blind, placebo controlled, multinational Phase II intermittent claudication (IC) clinical trial. We anticipate data readout in first half of 2018.

PLX R18 is also under development in a Phase I trial in the United States for incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). The FDA cleared our Investigational New Drug application to begin a Phase I trial of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT. We initiated the trial in fiscal year 2017.

In October 2017, we announced that we received approval from the Israel Ministry of Health to initiate a Phase I trial studying our PLX-R18 cell therapy as a treatment for insufficient hematopoietic recovery following HCT.

In October 2017, the nTRACK, a collaborative project carried out by an international consortium led by LEITAT, was awarded a Euro 6,800 (approximately \$8,000) non-royalty bearing grant. An amount of Euro 500 (approximately \$600) is a direct grant allocated to us. We also expects to benefit from cost savings resulting from grant amounts allocated to the other consortium members. Final approval of the grant is subject to the finalization of the consortium and Horizon 2020 grant agreements.

In September 2017, we signed an agreement with 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.

## RESULTS OF OPERATIONS THREE MONTHS ENDED SEPTEMBER 30, 2017 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2016.

### Research and Development Expenses, Net

Research and development expense, net (costs less participation and grants by the IIA and other parties) for the three months ended September 30, 2017 decreased by 6% from \$4,998,000 for the three months ended September 30, 2016 to \$4,677,000. This decrease is attributed to a decrease in subcontractors' expenses due to the completion of patient enrollment in the IC clinical trial, a decrease in pre-clinical activities and a decrease in materials consumption. In addition, we recognized participation of \$168,000 of the European Union with respect to the Horizon 2020 grant, which commenced in calendar year 2017. The decrease was offset by lower participation of the IIA in the three months ended September 30, 2017 compared to the three months ended September 30, 2016 (\$3,300,000 was approved in calendar year 2016 compared to \$1,500,000 that was approved in calendar year 2017) and an increase in payroll expenses mainly due to differences in exchange rates.

### General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2017 increased by 77% from \$1,564,000 for the three months ended September 30, 2016 to \$2,763,000, mainly due to an increase in stock-based compensation expenses related to the amount of restricted stock units granted, an increase in payroll expenses due to differences in exchange rates as well as an increase in the number of employees, and an increase in corporate activities expenses.

### Financial Income, Net

Financial income, net, decreased from a net financial income of \$238,000 for the three months ended September 30, 2016 to a net financial income of \$55,000 for the three months ended September 30, 2017. This decrease is mainly attributable to an expense of \$850,000 related to our marketable securities resulting from other-than-temporary impairment loss recognized in the three months ended September 30, 2017, increased expense related to the changes in the fair market value of our hedging instruments, which is related to the strength of the U.S. dollar against the NIS, and increased expense from exchange rates since through the three months ended September, 2017, there was an increase of 1% in the value of the U.S. dollar against the NIS, compared to a decrease of 2% in the value of the U.S. dollar against the NIS through the three months ended September 30, 2016. This decrease was partially offset by increased income related to the sale of our marketable securities.

### Net Loss

Net loss for the three month period ended September 30, 2017 was \$7,385,000, as compared to net loss of \$6,324,000 for the three month period ended September 30, 2016, the change was mainly due to the increase in general and administrative expenses, as described above. Net loss per share for each of the three month periods ended September 30, 2017 and September 30, 2016, was \$0.08.

For the three month periods ended September 30, 2017 and September 30, 2016, we had weighted average shares of common stock outstanding of 97,321,866 and 80,674,961, 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 issuance of additional shares, mainly related to the issuances of shares from a public offering we conducted in January 2017, issuances of shares to employees and consultants, issuances of shares pursuant to our At Market Issuance Sales Agreement, or the ATM Agreement, and shares issued as a result of exercises of options and warrants.

### Liquidity and Capital Resources

As of September 30, 2017, our total current assets were \$22,841,000 and total current liabilities were \$4,771,000. On September 30, 2017, we had a working capital surplus of \$18,070,000, stockholders' equity of \$24,364,000 and an accumulated deficit of \$196,956,000. We finance our operations, and plan to continue doing so, from our existing cash, issuances of our securities, sales of the marketable securities we hold and funds from grants from the IIA, Israel's Ministry of Economy, European Union and other research grants.

Our cash and cash equivalents as of September 30, 2017 amounted to \$12,294,000 compared to \$6,098,000 as of September 30, 2016, and compared to \$4,707,000 as of June 30, 2017. Cash balances changed in the three months ended September 30, 2017 and 2016 for the reasons presented below.

Operating activities used cash of \$5,190,000 in the three months ended September 30, 2017, compared to \$3,923,000 in the three months ended September 30, 2016. Cash used in operating activities in the three months ended September 30, 2017 and 2016 consisted primarily of payments of salaries to our employees and payments of fees to our consultants, suppliers, subcontractors, and professional services providers, including the costs of clinical studies, offset by grants from the IIA and Israel's Ministry of Economy.

Investing activities provided cash of \$11,727,000 in the three months ended September 30, 2017, compared to \$3,794,000 for the three months ended September 30, 2016. The investing activities in the three months ended September 30, 2017 consisted primarily of \$9,019,000 provided from the sale and redemption of marketable securities, and the withdrawal of \$4,002,000 of short term deposits, offset by investment of \$1,146,000 in marketable securities and payments of \$148,000 related to investment in property and equipment. The investing activities in the three months ended September 30, 2016 consisted primarily of the withdrawal of \$1,834,000 of short term deposits and \$2,787,000 provided from the sale and redemption of marketable securities, offset by investment of \$686,000 in marketable securities and payments of \$145,000 related to investment in property and equipment.

Financing activities generated cash of \$1,050,000 during the three months ended September 30, 2017, compared to \$4,000 for the three months ended September 30, 2016. The cash generated in the three months ended September 30, 2017 from financing activities is related to net proceeds of \$1,026,000 from issuing shares of our common stock under our ATM Agreement and from the exercise of warrants. The cash generated in the three months ended September 30, 2016 from financing activities was related to exercises of options by employees.

In July 2017, we entered into the ATM Agreement with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc., each an Agent, which provides that, upon the terms and subject to the conditions and limitations set forth in the ATM Agreement, we may elect, from time to time, to issue and sell shares of common stock having an aggregate offering price of up to \$80 million through any of the Agents. We are not obligated to make any sales of common stock under the ATM Agreement. During the three month period ended September 30, 2017, we sold 834,040 shares of common stock pursuant to the ATM Agreement at an average price of \$1.33 per share.

During the three months ended September 30, 2017, we received cash of approximately \$1,349,000 from the IIA towards our research and development expenses. According to the IIA grant terms, we are required to pay royalties at a rate of 3% - 4% 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 30, 2017, total grants obtained from the IIA aggregated to approximately \$28,818,000 and total royalties paid amounted to \$166,000.

The IIA has supported our activity in the past twelve years. Our last program, for the twelfth year, was approved by the IIA in 2017 and relates to an approximately \$1,500,000 grant. The grant will be used to cover research and development expenses for the period January 1, 2017 to December 31, 2017.

Through September 30, 2017, we received total grants of approximately \$965,000 in cash from the European Union research and development consortium under the Horizon 2020 program.

The currency of our financial portfolio is mainly in U.S. dollars and we use options contracts 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 our 2016 Annual Report.

We have an effective Form S-3 registration statement, filed under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf registration process, we may, from time to time, sell common stock, preferred stock and warrants to purchase common stock, and units of two or more of such securities in one or more offerings up to a total dollar amount of \$200,000,000. As of November 2, 2017, we have been deemed to have sold \$80,000,000 pursuant to our existing shelf, which is allocated for our ATM Agreement. In addition, on October 31, 2017, we completed a public offering in Israel, pursuant to our existing shelf in the United States and a shelf registration statement filed in Israel, pursuant to which we raised aggregate gross proceeds of \$15,051,000 through the sale of 9,000,000 shares of our common stock at a purchase price of \$1.67 per share. The net proceeds, after deducting fees and estimated expenses were \$13,674,000.

## Outlook

We have accumulated a deficit of \$196,956,000 since our inception in May 2001. We do not expect to generate any revenues from sales of products in the next twelve months. Our cash needs will increase in the foreseeable future. We expect to generate revenues, which in the short and medium terms will unlikely exceed our costs of operations, from the sale of licenses to use our technology or products.

We will 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 IIA grants, the European Union grant and other research grants, sales of our common stock or sales of the marketable securities we hold.

As of September 30, 2017, our cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$20,746,000. We are addressing our liquidity issues by implementing initiatives to allow the continuation of our activities. Our current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures. Our ability to successfully carry out our business plan, which includes a cost-reduction plan should we be unable to raise sufficient additional capital, is primarily dependent upon our ability to (1) obtain sufficient additional capital, (2) entering into license agreements to use or commercialize our products and (3) receive other sources of funding, including non-diluting sources such as the IIA grants, the Horizon 2020 grant and other grants. There are no assurances, however, that we will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of our products.

According to management's estimates, liquidity resources as of September 30, 2017, together with the funds received from the public offering we closed on October 31, 2017, will be sufficient to maintain our operations into the third quarter of fiscal year 2019. Our inability to raise funds to carry out our business plan will have a severe negative impact on our ability to remain a viable company.

## Off Balance Sheet Arrangements

We have no off balance sheet arrangements.

## 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 Co-Chief Executive Officers, or Co-CEOs, 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 Co-CEOs 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 Co-CEOs 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 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 6. Exhibits.

[31.1\\*](#) [Rule 13a-14\(a\) Certification of Co-Chief Executive Officer.](#)

[31.2\\*](#) [Rule 13a-14\(a\) Certification of Co-Chief Executive Officer.](#)

[31.3\\*](#) [Rule 13a-14\(a\) Certification of Chief Financial Officer.](#)

[32.1\\*\\*](#) [Certification of Co-Chief Executive Officer pursuant to 18 U.S.C. Section 1350.](#)

[32.2\\*\\*](#) [Certification of Co-Chief Executive Officer pursuant to 18 U.S.C. Section 1350.](#)

[32.3\\*\\*](#) [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, 2017 formatted in XBRL (eXtensible Business Reporting Language): (i) the Interim Condensed Consolidated Balance Sheets, (ii) the Interim Condensed Consolidated Statements of Operations, (iii) the Interim Condensed Consolidated Statements of Comprehensive Loss, (iv) the Interim Condensed Statements of Changes in Equity, (v) 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.

\*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.

### PLURISTEM THERAPEUTICS INC.

By: /s/ Zami Aberman

Zami Aberman, Co-Chief Executive Officer

(Principal Executive Officer)

Date: November 7, 2017

By: /s/ Yaky Yanay

Yaky Yanay, Co-Chief Executive Officer and President

(Principal Executive Officer)

Date: November 7, 2017

By: /s/ Erez Egozi

Erez Egozi, Chief Financial Officer, (Principal Financial Officer and Principal Accounting Officer)

Date: November 7, 2017



**CERTIFICATION**

I, Zami Aberman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluristem Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(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 13(a)-15(f) and 15d-15(f)) of 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 7, 2017

/s/ Zami Aberman

---

Zami Aberman  
Co-Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION**

I, Yaky Yanay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluristem Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(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 13(a)-15(f) and 15d-15(f)) of 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 7, 2017

/s/ Yaky Yanay

\_\_\_\_\_  
Yaky Yanay  
Co-Chief Executive Officer and President  
(Principal Executive Officer)

---

**CERTIFICATION**

I, Erez Egozi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluristem Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(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 13(a)-15(f) and 15d-15(f)) of 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 7, 2017

/s/ Erez Egozi

\_\_\_\_\_  
Erez Egozi  
Chief Financial Officer  
(Principal Financial Officer)

---

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

In connection with the Quarterly Report (the "Report") of Pluristem Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof, I, Zami Aberman, Co-Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, 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.

Date: November 7, 2017

By: /s/ Zami Aberman

\_\_\_\_\_  
Zami Aberman  
Co-Chief Executive Officer

---

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

In connection with the Quarterly Report (the "Report") of Pluristem Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof, I, Yaky Yanay, Co-Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, 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.

Date: November 7, 2017

By: /s/ Yaky Yanay

\_\_\_\_\_  
Yaky Yanay  
Co-Chief Executive Officer and President

---

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

In connection with the Quarterly Report (the "Report") of Pluristem Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof, I, Erez Egozi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, 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.

Date: November 7, 2017

By: /s/ Erez Egozi

\_\_\_\_\_  
Erez Egozi  
Chief Financial Officer

---