

PLURISTEM THERAPEUTICS INC

Form 10-Q

May 09, 2016

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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

☐ 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	98-0351734
(State or other jurisdiction of incorporation or organization)	(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 filer, a non-accelerated filer,

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-Q

or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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: 80,161,613 shares of common stock issued and outstanding as of May 2, 2016.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

As of March 31, 2016

(Unaudited)

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

As of March 31, 2016

U.S. DOLLARS IN THOUSANDS

(Unaudited)

INDEX

	Page
<u>Interim Condensed Consolidated Balance Sheets</u>	F - 2 - F- 3
<u>Interim Condensed Consolidated Statements of Operations</u>	F - 4
<u>Interim Condensed Consolidated Statements of Comprehensive Loss</u>	F - 5
<u>Interim Condensed Statements of Changes in Equity</u>	F - 6 - F - 7
<u>Interim Condensed Consolidated Statements of Cash Flows</u>	F - 8 - F - 9
<u>Notes to Interim Condensed Consolidated Financial Statements</u>	F - 10 - F - 22

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	March 31, 2016 Unaudited	June 30, 2015
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$5,404	\$22,626
Short-term bank deposits		11,258	7,167
Restricted cash and short-term bank deposits		542	1,076
Marketable securities	3	20,768	22,250
Account receivable from the Office of the Chief Scientist		180	1,691
Other account receivable		975	2,058
Total current assets		39,127	56,868
LONG-TERM ASSETS:			
Long-term deposits and restricted deposits		369	361
Severance pay fund		770	753
Property and equipment, net		9,719	10,173
Total long-term assets		10,858	11,287
Total assets		\$49,985	\$68,155

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	March 31, 2016 Unaudited	June 30, 2015
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		\$1,968	\$3,268
Accrued expenses		1,157	910
Deferred revenues	1c	-	379
Advance payment from United Therapeutics	1c	-	93
Other accounts payable		1,683	1,533
Total current liabilities		4,808	6,183
LONG-TERM LIABILITIES			
Deferred revenues	1c	-	2,468
Accrued severance pay		912	859
Other long-term liabilities		1,159	502
Total long-term liabilities		2,071	3,829
COMMITMENTS AND CONTINGENCIES	5		
STOCKHOLDERS' EQUITY			
Share capital:	6		
Common stock \$0.00001 par value:			
Authorized: 200,000,000 shares			
Issued and outstanding: 80,079,831 shares as of March 31, 2016, 78,771,905 shares as of June 30, 2015		1	1
Additional paid-in capital		197,726	195,303
Accumulated deficit		(155,552)	(138,511)
Receivables on account of shares		-	(790)
Other comprehensive income		931	2,140
Total stockholders' equity		43,106	58,143
Total liabilities and stockholders' equity		\$49,985	\$68,155

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Note	Nine months ended March 31,		Three months ended March 31,	
		2016	2015	2016	2015
Revenues	1c	\$2,847	\$285	\$-	\$95
Cost of revenues		(100)	(10)	-	(3)
Gross profit		2,747	275	-	92
Operating Expenses:					
Research and development expenses		(16,427)	(17,303)	(5,797)	(6,182)
Less participation by the Office of the Chief Scientist and other parties		1,206	2,293	41	88
Research and development expenses, net		(15,221)	(15,010)	(5,756)	(6,094)
General and administrative expenses		(4,672)	(4,718)	(1,639)	(1,527)
Operating loss		(17,146)	(19,453)	(7,395)	(7,529)
Financial income, net		105	71	192	303
Net loss for the period		\$(17,041)	\$(19,382)	\$(7,203)	\$(7,226)
Loss per share:					
Basic and diluted net loss per share		\$(0.21)	\$(0.28)	\$(0.09)	\$(0.10)
Weighted average number of shares used in computing basic and diluted net loss per share		79,350,504	69,954,373	79,935,477	70,668,008

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

U.S. Dollars in thousands

	Nine months ended March 31,		Three months ended March 31,	
	2016	2015	2016	2015
Net loss	\$(17,041)	\$(19,382)	\$(7,203)	\$(7,226)
Other comprehensive loss, net:				
Unrealized losses on derivative instruments	-	(337)	-	(70)
Unrealized gains (losses) on available-for-sale marketable securities, net	(1,466)	(1,690)	(120)	2,228
Reclassification adjustment of derivative instruments gains (losses) realized in net loss, net	(46)	274	-	73
Reclassification adjustment of available-for-sale marketable securities gains (losses) realized in net loss, net	303	290	283	(336)
Other comprehensive income (loss)	(1,209)	(1,463)	163	1,895
Total comprehensive loss	\$(18,250)	\$(20,845)	\$(7,040)	\$(5,331)

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

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

	Common Stock		Additional	Receivables	Accumulated		Total
	Shares	Amount	Paid-in	on	Other	Accumulated	Stockholders'
			Capital	account	Comprehensive	Deficit	Equity
				of shares	Income		
					(Loss)		
Balance as of July 1, 2014	68,601,452	\$ (*)	\$ 172,998	-	\$ 2,959	\$ (113,834)	\$ 62,123
Exercise of options by employees	8,000	(*)	7	-	-	-	7
Exercise of warrants by investors and finders	841,993	(*)	244	-	-	-	244
Stock-based compensation to employees, directors and non-employee consultants	1,091,562	(*)	2,912	-	-	-	2,912
Issuance of common stock in a private placement (Note 6a)	400,000	(*)	1,114	-	-	-	1,114
Stock-based compensation to contractor (Note 6b)	100,004	(*)	-	-	-	-	-
Other comprehensive loss, net	-	-	-	-	(1,463)	-	(1,463)
Net loss	-	-	-	-	-	(19,382)	(19,382)
Balance as of March 31, 2015 (unaudited)	71,043,011	\$ (*)	\$ 177,555	\$ (280)	\$ 1,496	\$ (133,216)	\$ 45,555

(*) Less than \$1

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

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

	Common Stock		Additional	Receivables	Accumulated		Total
	Shares	Amount	Paid-in	on	Other	Accumulated	Stockholders'
			Capital	account	Comprehensive	Deficit	Equity
				of shares	Income		
					(Loss)		
Balance as of July 1, 2015	78,771,905	\$ 1	\$ 195,303	\$ (790)	\$ 2,140	\$ (138,511)	\$ 58,143
Exercise of options by employees and non-employee consultants	28,000	(*)	17	-	-	-	17
Stock-based compensation to employees, directors and non-employee consultants	1,189,926	(*)	2,367	-	-	-	2,367
Proceeds related to issuance of common stock in a private placement (Note 6a)	-	-	-	790	-	-	790
Stock-based compensation to contractor (Note 6b)	90,000	-	39	-	-	-	39
Other comprehensive loss, net	-	-	-	-	(1,209)	-	(1,209)
Net loss	-	-	-	-	-	(17,041)	(17,041)
Balance as of March 31, 2016 (unaudited)	80,079,831	\$ 1	\$ 197,726	\$ -	\$ 931	\$ (155,552)	\$ 43,106

(*) Less than \$1

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Nine months ended March 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(17,041)	\$(19,382)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,590	1,498
Loss from sale of property and equipment, net	(3)	-
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	41	233
Gain from sale of investments of available-for-sale marketable securities	303	290
Stock-based compensation to employees, directors and non-employees consultants	2,367	2,912
Decrease in Office of the Chief Scientist receivables	1,511	2,059
Decrease (increase) in other accounts receivable	1,038	(641)
Decrease in trade payables	(888)	(836)
Increase (decrease) in other accounts payable, accrued expenses and other long-term liabilities	1,054	(1,267)
Decrease in deferred revenues	(2,847)	(285)
Decrease in advance payment from United Therapeutics	(93)	(123)
Increase in interest receivable on short-term deposits	(33)	19
Linkage differences and interest on short and long-term deposits	(13)	(5)
Accrued severance pay, net	36	(60)
Net cash used by operating activities	\$(12,978)	\$(15,588)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	\$(1,535)	\$(638)
Repayment of (investment in) short-term deposits	(3,524)	12,511
Repayment of long-term deposits	4	10
Proceeds from sale of property and equipment	29	-
Proceeds from sale of available-for-sale marketable securities	2,863	9,879
Proceeds from redemption of available-for-sale marketable securities	1,066	440
Investment in available-for-sale marketable securities	(3,954)	(3,528)
Net cash provided by (used in) investing activities	\$(5,051)	\$18,674

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Nine months ended March 31,	
	2016	2015
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds related to issuance of common stock in a private placement	\$790	\$1,114
Exercise of options and warrants	17	251
Net cash provided by financing activities	\$807	\$1,365
Increase (decrease) in cash and cash equivalents	(17,222)	4,451
Cash and cash equivalents at the beginning of the period	22,626	4,493
Cash and cash equivalents at the end of the period	\$5,404	\$8,944
(a) Supplemental disclosure of cash flow activities:		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$50	\$47
(b) Supplemental disclosure of non-cash activities:		
Purchase of property and equipment on credit	\$200	\$9
Share consideration to contractor	\$39	\$-

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

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 “Pluristem” or the “Company”.

b. The Company is a bio-therapeutics company developing off-the-shelf allogeneic cell therapy products for the treatment of multiple ischemic and inflammatory conditions. The Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated losses aggregated to \$155,552 through March 31, 2016 and the Company incurred a net loss of \$17,041 for the nine months ended March 31, 2016.

The Company plans to continue to finance its operations with sales of equity securities, entering into licensing technology agreements (see Note 1c) and from grants to support its research and development activity. In the longer term, the Company plans to finance its operations from revenues from sales of products.

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”.

c. License Agreements:

United Therapeutics Corporation ("United") Agreement

On June 19, 2011, the Company entered into an exclusive license agreement (the “United Agreement”) with United for the use of the Company's PLX cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension (“PAH”). The United Agreement provided that United would receive exclusive worldwide license rights for the development and commercialization of the Company's PLX cell-based product to treat PAH. The United Agreement further provided for the following consideration payable to the Company: (i) an upfront payment of \$7,000 paid in August 2011, which included a \$5,000 non-refundable upfront payment and a \$2,000 advance payment on the development; (ii) up to \$37,500 upon reaching certain regulatory milestones with respect to the development of a product to treat PAH; (iii) reimbursement of up to \$10,000 of certain of the Company's expenses if the Company establishes a GMP manufacturing facility in North America; (iv) reimbursement of certain costs in connection with the development of the product; and (v) following commercialization of the product, royalties at a mid-single digit percent and the purchase of commercial supplies of the developed product from the Company at a specified margin over the Company's cost.

On December 8, 2015, the Company received a notice from United terminating the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, Pluristem regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. As the Company has no further obligations towards United, the Company recognized the remaining upfront payment received in August 2011 as revenues during the nine month period ended March 31, 2016.

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, and Intermediate Claudication (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.

F - 10

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

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 this CHA Agreement, the license granted thereunder will terminate and all rights included therein will revert to the Company, whereupon 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 ASC 320- "Investments - Debt and Equity Securities". The fair value of the remaining investment as of March 31, 2016, is \$4,820.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND 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, 2015.

Operating results for the three and nine month periods ended March 31, 2016, are not necessarily indicative of the results that may be expected for the year ending June 30, 2016.

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 and assumptions that 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, trade payable and other accounts payable and accrued 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.

F - 12

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (CON.)

e. Derivative financial instruments

The Company uses forward contracts and options strategies (“derivative instruments”) primarily to manage exposure to foreign currency. The Company accounts for derivatives and hedging based on ASC 815, “Derivatives and Hedging” (“ASC 815”). ASC 815 requires the Company to recognize all derivative instruments as either assets or liabilities on the balance sheet at fair value. The accounting for changes in the fair value (i.e., gains or losses) of derivative instruments depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must designate the hedging instrument, based upon the exposure being hedged, as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation.

If the derivative instruments meet the definition of a hedge and are so designated, depending on the nature of the hedge, changes in the fair value of such derivatives will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings, or recognized in other comprehensive income until the hedged item is recognized in the statement of operations. The ineffective portion of a derivative’s change in fair value is recognized in the statement of operations.

Cash Flow Hedges. The Company entered into forward and option contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses denominated in New Israeli Shekels (“NIS”). The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). The gain or loss on the effective portion of a cash flow hedge is initially reported as a component of accumulated other comprehensive income and subsequently reclassified into operating expenses in the same period or periods in which the payroll and related expenses are recognized, or reclassified into “Financial expense, net”, if the hedged transaction becomes probable of not occurring. Any gain or loss after a hedge is no longer designated, because it is no longer probable of occurring or it is related to an ineffective portion of a cash flow hedge is recognized in the statement of operations immediately. The net loss realized in statement of operations during the three and nine month periods ended March 31, 2016 and 2015, resulting from the cash flow hedge transactions, amounted to approximately \$0, \$7, and \$73, \$274, respectively.

Other Derivatives. Other derivatives that are non-designated consist primarily of options strategies to minimize the risk associated with the foreign exchange effects of monetary assets and liabilities denominated in NIS. The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). The net gains (losses) recognized in “Financial income, net”, during the three and nine month periods ended March 31, 2016 and 2015, were \$221 , (\$26) and \$98, (\$41), respectively.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (CON.)

f. Accumulated other comprehensive income (loss):

The components of accumulated other comprehensive income (loss) were as follows:

	Nine months ended March 31, 2016 (Unaudited)		
	Unrealized gains (losses) on marketable securities	Unrealized gains (losses) on cash flow hedges	Total
Balance as of July 1, 2015	\$ 2,094	\$ 46	\$ 2,140
Other comprehensive loss before reclassifications	(1,466)	-	(1,466)
Amounts reclassified from accumulated other comprehensive loss	303	(46)	257
Net current-period other comprehensive income	(1,163)	(46)	(1,209)
Balance as of March 31, 2016	\$ 931	\$ (-)	\$ 931

g. Recently Issued Accounting Standards:

ASU 2014-15 – Presentation of Financial Statements-Going Concern (Subtopic 205-40):

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted.

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. ASC 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.

F - 14

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES (CON.)

g. Recently Issued Accounting Standards (con.):

ASU 2014-09 - Revenue from Contracts with Customers (Topic 606):

In May 2014, the FASB issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The guidance permits the use of either a retrospective or cumulative effect transition method. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 3:- MARKETABLE SECURITIES

As of March 31, 2016, all of the Company's marketable securities were classified as available-for-sale.

	March 31, 2016 (Unaudited)				June 30, 2015			
	Amortized	Gross	Gross	Fair	Amortized	Gross	Gross	Fair
	cost	unrealized	unrealized	Value	cost	unrealized	unrealized	value
		gain	loss			gain	loss	
Available-for-sale - matures within one year:								
Stock and index linked notes	\$12,186	\$ 1,334	\$ (531)	\$12,989	\$12,305	\$ 2,083	\$ (72)	\$14,316
Government debentures – fixed interest rate	1,371	19	-	1,390	287	1	(10)	278
Corporate debentures – fixed interest rate	725	11	-	736	939	26	(52)	913
	\$14,282	\$ 1,364	\$ (531)	\$15,115	\$13,531	\$ 2,110	\$ (134)	\$15,507
Available-for-sale - matures after one year through five years:								
Government debentures – fixed interest rate	455	9	-	464	2,033	40	(9)	2,064
Corporate debentures – fixed interest rate	4,793	78	(2)	4,869	4,436	97	(17)	4,516
	\$5,248	\$ 87	\$ (2)	\$5,333	\$6,469	\$ 137	\$ (26)	\$6,580
Available-for-sale - matures after five years through ten years:								
Government debentures – fixed interest rate	266	11	-	277				
Corporate debentures – fixed interest rate	41	2	-	43	156	8	(1)	163
	\$307	\$ 13	\$ -	\$320	\$156	\$ 8	\$ (1)	\$163
	\$19,837	\$ 1,464	\$ (533)	\$20,768	\$20,156	\$ 2,255	\$ (161)	\$22,250

The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of March 31, 2016 and June 30, 2015, and the length of time that those investments have been in a continuous loss position:

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-Q

	Less than 12 months		12 months or greater	
	Gross		Gross	
	unrealized		unrealized	
	Fair Value	loss	Fair Value	loss
As of March 31, 2016 (Unaudited)	\$6,620	\$(460)	\$373	\$(73)
As of June 30, 2015	\$2,535	\$(107)	\$524	\$(54)

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 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 did not recognize any impairment charges on outstanding securities during the three and nine month periods ended March 31, 2016.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

	March 31, 2016 (Unaudited)		June 30, 2015	
	Level 1	Level 2	Level 1	Level 2
Marketable securities	\$10,260	\$10,508	\$12,650	\$9,600
Foreign currency derivative instruments	-	244	-	322
Total financial assets	\$10,260	\$10,752	\$12,650	\$9,922

	March 31, 2016 (Unaudited)		June 30, 2015	
	Balance Sheet location	Fair Value	Balance Sheet location	Fair Value
Derivatives designated as a cash flow hedge instruments		\$ -	Other account receivable	\$ 52
Derivatives not designated as hedge instruments	Other account receivable	\$ 244	Other account receivable	\$ 270
Total		\$ 244		\$ 322

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 5: - COMMITMENTS AND CONTINGENCIES

Commitments and contingencies that changed during the nine month period ended March 31, 2016, include the following:

- a. Decrease of \$521 of cash pledged by the Company to secure its hedging transactions, credit line and bank guarantees.
- 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 a governmental committee of the Office of the Chief Scientist of Israel ("OCS") 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 Chief Scientist of 3% to 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. The outstanding balance of the grants will be subject to interest at a rate equal to the 12 month LIBOR applicable to dollar deposits that is published on the first business day of each calendar year. Following the full repayment of the grant, there is no further liability for royalties.

Through March 31, 2016, total grants obtained aggregated to approximately \$21,183, and total royalties paid and accrued amounted to \$166. As of March 31, 2016, the Company's contingent liability in respect to royalties to the OCS amounted \$21,017, not including LIBOR interest as described above.

NOTE 6: - STOCKHOLDERS' EQUITY

From October 2014 through May 2015, the Company issued shares of common stock in private placements to an investor. In October 2014, the Company issued 200,000 shares of common stock to an investor for aggregate cash consideration of \$528. In February 2015, the Company issued an additional 200,000 shares of common stock to an investor for aggregate cash consideration of \$586. In May 2015, the Company issued an additional 300,000 shares of common stock to an investor, for which the consideration in the amount of \$790 was received from the investor in September 2015.

In February 2015, the Subsidiary entered into an agreement with a contractor for the construction of its new laboratories facility for a consideration of approximately NIS 3.3 million (approximately \$841). Under the terms of the agreement, the Subsidiary will pay part of the NIS 3.3 million consideration using 100,004 restricted shares of common stock of the Company, linked to performance milestones with respect to the new laboratories construction and which serve as a guarantee. These restricted shares shall be released to the contractor only upon the successful completion of the construction. The restricted shares were issued in December 2014.

In May 2015, the Subsidiary entered into an addendum to the agreement with the contractor for the design and construction of additional office space renovations in the Subsidiary leased facility for additional consideration of approximately NIS 4 million (approximately \$1,032) which is comprised of NIS 3 million (approximately \$774) in cash and 90,000 restricted shares which were issued to the contractor in February 2016.

The Company accounted for the abovementioned stock-based payment awards to the contractor in accordance with ASC 505-50, "Equity based payments to non-employees". As performance by the contractor is not complete if the awards are forfeitable (or not issued) in the event performance not completed, the Company measured the fair value of the awards at each reporting period through the performance completion date (until completion of the construction work).

F - 18

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

The construction work was initiated in June 2015. On October 30, 2015, the contractor completed the agreed construction milestones. As a result, the Company recognized the fair value of the stock-based payments awards, using the fair value of the Company's shares on October 30, 2015, totaling approximately \$302 as stock-based payment to the contractor in "Additional paid-in capital" with a corresponding amount included in "Property and equipment, net".

c. Options, warrants and restricted stock units 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:

Nine months ended March 31, 2016 (Unaudited)				
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	1,836,900	\$ 3.72		
Options forfeited	(37,200)	\$ 4.40		
Options exercised	(28,000)	\$ 0.62		
Options outstanding at end of the period	1,771,700	\$ 3.76	1.40	\$ 382
Options exercisable at the end of the period	1,771,700	\$ 3.76	1.40	\$ 382
Options vested	1,771,700	\$ 3.76	1.40	\$ 382

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 March 31, 2016. This amount changes based on the fair market value of the Company's common stock.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

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

2. Options and warrants to non-employees:

A summary of the activity for options and warrants to non-employees consultants is as follows:

Nine months ended March 31, 2016 (Unaudited)				
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options and warrants outstanding at beginning of period	228,000	\$ 5.19		
Options granted	1,800	\$ 0.00		
Options forfeited	(6,000)	\$ 4.40		
Options and warrants outstanding at end of the period	223,800	\$ 5.72	2.23	\$ 133
Options and warrants exercisable at the end of the period	221,500	\$ 5.78	2.16	\$ 131
Options not vested, expected to vest	2,300	\$ 0.00	8.78	\$ 2

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

	Nine months ended March 31,		Three months ended March 31,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ -	\$ 1	\$ -	\$ -
General and administrative expenses	\$ 2	\$ 1	\$ 1	\$ 1
	\$ 2	\$ 2	\$ 1	\$ 1

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

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

3. Restricted stock units to employees and directors:

The following table summarizes the activity related to unvested restricted stock units granted to employees and directors for the nine month period ended March 31, 2016 (Unaudited):

	Number
Unvested at the beginning of period	1,732,383
Granted	1,461,431
Forfeited	(78,601)
Vested	(1,009,783)
Unvested at the end of the period	2,105,430
Expected to vest after March 31, 2016	2,028,054

Compensation expenses related to restricted stock units granted to employees and directors were recorded as follows:

	Nine months ended March 31,		Three months ended March 31,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 743	\$ 977	\$ 260	\$ 482
General and administrative expenses	1,496	1,735	476	592
	\$ 2,239	\$ 2,712	\$ 736	\$ 1,074

Unamortized compensation expenses related to restricted stock units granted to employees and directors to be recognized over an average time of approximately 1.83 years is approximately \$1,676.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL
STATEMENTS

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

NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

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

4. Restricted stock and restricted stock units to consultants:

The following table summarizes the activity related to unvested restricted stock and restricted stock units granted to consultants for the nine months ended March 31, 2016 (Unaudited):

	Number
Unvested at the beginning of period	28,385
Granted	152,257
Vested	(180,142)
Unvested at the end of the period	500

Compensation expenses related to restricted stock and restricted stock units granted to consultants were recorded as follows:

	Nine months ended March 31,		Three months ended March 31,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 26	\$ 110	\$ 6	\$ 33
General and administrative expenses	100	88	52	50
	\$ 126	\$ 198	\$ 58	\$ 83

NOTE 7:-SUBSEQUENT EVENTS

In May 2016, the Subsidiary received an approval for a NIS 12,700 (approximately \$3,300) grant from the OCS. Once received, the grant will be used to cover research and development expenses for the period from January 1, 2016 to December 31, 2016. This grant is subject to the same repayment restrictions of royalties as the prior OCS grants (see note 5.b.).

Since the approval was received after March 31, 2016, the grant is not reflected in the financial statements.

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 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 and conclusion of trials;
- achieving regulatory approvals, including under accelerated paths;
- receipt of future funding from the Office of the Chief Scientist of Israel;
- 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 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; 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, 2015, or the 2015 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

We are a bio-therapeutics company developing off-the-shelf allogeneic cell therapy products for the treatment of multiple ischemic and inflammatory conditions, with our lead indications focusing on cardiovascular, orthopedic, pulmonary, hematological, and women's health diseases. Our patented placenta expanded, or PLX, cells are intended to function as a platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals that are generated by the patient's own body. PLX cells are grown using our proprietary three-dimensional, or 3D, micro environment technology which produces a product that requires no tissue matching prior to administration.

We were incorporated as a Nevada corporation in 2001. We have a wholly owned subsidiary in Israel called Pluristem Ltd., or the Subsidiary. We operate in one segment and our operations are focused on the research, development, clinical trials and manufacturing of cell therapeutics and related technologies.

Our strategy is to develop and produce cell therapy products for the treatment of multiple disorders using several routes of administration, such as intravenous and intramuscular injections. We plan to execute this strategy independently, using our own personnel, and through relationships with research and clinical institutions or in collaboration with other companies. We have built a facility that complies with current Good Manufacturing Practice requirements and we are planning to have in-house production capacity to grow clinical grade PLX cells in commercial quantities.

Our focus is to make significant progress in our clinical pipeline and shorten the time to market our first product, PLX-PAD, in Europe and Japan, in parallel to our clinical trials in the United States, South Korea and Israel. We intend to leverage the new regulatory environments in Europe and Japan that now offer unique opportunities for accelerated paths to bring new products to the market. We believe that these new pathways create substantial opportunities for us and for the cell therapy industry as a whole. We will explore these accelerated pathways for several of our current clinical indications, such as critical limb ischemia, or CLI, as well as incomplete hematopoietic recovery following Hematopoietic Cell Transplantation, or HCT, which our second product, PLX-R18, is expected to address.

In May 2015, we announced that the PLX cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines Agency. In addition, we reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) 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. Our intention is to initiate the CLI studies during calendar year 2016 with the aim of obtaining initial approval in calendar year 2018.

We plan to continue developing multiple placenta-derived cell therapy products that we anticipate will lead to significant improvement in the lives of patients, and expect to demonstrate the real-world data impact and value of our pipeline, technology platform and commercial-scale manufacturing capacity. We made progress in our Phase II intermittent claudication, or IC, trial, a randomized, double blind, placebo controlled, multinational clinical trial. We expect to complete the enrollment in the IC trial during the next few months. We currently have active clinical sites in the United States, Israel, Germany and South Korea.

In December 2015, the U.S. Food and Drug Administration, or FDA, granted our PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia. We are currently conducting additional pre-clinical studies to set the pathway towards clinical studies.

On December 8, 2015, we received a notice from United Therapeutics Corporation, or United, terminating our exclusive license agreement with United, or the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, we regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. In the coming months we will analyze the clinical data and decide how to move forward with the clinical development of the program including seeking other licensing partners. 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 plan to initiate the clinical trial in the United States in the next few months.

In February 2016, we announced that the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the U.S. National Institutes of Health, will initiate studies in large animals to evaluate dosing for our PLX-R18 as a medical counter measure in the treatment of the hematologic components of Acute Radiation Syndrome, or ARS. Once the optimal dose is determined in large animals, a pivotal trial could be conducted, the results of which may be used to support a Biologics License Application submission of PLX-R18 for this indication under the Animal Rule regulatory pathway. In September 2015, the FDA confirmed that data from earlier trials conducted by NIAID were sufficient for the future design of studies in the development path for PLX-R18. NIAID supports and collaborates on the dosing studies, and we supply PLX-R18 cells.

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.

We plan to evaluate in the upcoming months the timing to initiate our advanced orthopedic indications, based on potential partnering interest as well as regulatory approvals for early access to the market.

RESULTS OF OPERATIONS – NINE AND THREE MONTHS ENDED MARCH 31, 2016 COMPARED TO NINE AND THREE MONTHS ENDED MARCH 31, 2015.

Revenues

Revenues for the nine and three month periods ended March 31, 2016, and for the nine and three month periods ended March 31, 2015 were \$2,847,000, \$0 and \$285,000, \$95,000, respectively. All such revenues are derived from the United Agreement.

On December 8, 2015, we received a notice from United terminating the United Agreement, effective immediately. As we have no further obligations towards United, we recognized the remaining upfront payment received in August 2011 as revenues during the nine month period ended March 31, 2016.

Research and Development Expenses, Net

Research and development expense, net (costs less participation and grants by the Office of the Chief Scientist of Israel, or OCS, and other parties) for the nine months ended March 31, 2016 increased by 1% from \$15,010,000 for the nine months ended March 31, 2015 to \$15,221,000. This increase is attributed to a decrease in OCS participation, which was lower in calendar year 2015 compared to calendar year 2014 (\$4,200,000 was approved in calendar year 2014 compared to \$2,900,000 that was approved in calendar year 2015). The reduced OCS participation was offset by an improved planning of our production process, resulting in a decrease in materials consumption, maintenance and overhead, and by a decrease in stock-based compensation expenses due to the decrease in the market value of our common stock.

Research and development expense, net (costs less participation and grants by the OCS and other parties) for the three months ended March 31, 2016 decreased by 6% from \$6,094,000 for the three months ended March 31, 2015 to \$5,756,000. This decrease is attributed to a decrease in stock-based compensation expenses due to the decrease in the market value of our common stock, and a decrease in our materials consumption and patent expenses.

General and Administrative Expenses

General and administrative expenses for the nine months ended March 31, 2016 decreased by 1% from \$4,718,000 for the nine months ended March 31, 2015 to \$4,672,000, mainly due to a decrease in stock-based compensation expenses

related to our directors and officers and attributable to the timing of the grants under the option plan and the market value of our common stock on day of the grant, offset by an increase in corporate activities.

General and administrative expenses for the three months ended March 31, 2016 increased by 7% from \$1,527,000 for the three months ended March 31, 2015 to \$1,639,000, mainly due to an increase in corporate activities, offset by a decrease in stock-based compensation expenses due to the decrease in the market value of our common stock.

Financial Income, Net

Financial income, net, increased by 48% from \$71,000 for the nine months ended March 31, 2015 to \$105,000 for the nine months ended March 31, 2016. This increase is mainly attributable to a decrease in our exchange rate expenses related to the strength of the U.S. dollar against the New Israeli Shekel, or NIS, in the nine months ended March 31, 2016, compared to the nine months ended March 31, 2015. This decrease was offset by lower income related to our marketable securities (such as net gains related to sales of the marketable securities, interest and dividend income).

Financial income, net, decreased by 37% from \$303,000 for the three months ended March 31, 2015 to \$192,000 for the three months ended March 31, 2016. This decrease is mainly attributable to lower income related to our marketable securities (such as net gains related to sales of the marketable securities, interest and dividend income), offset by increased income from exchange rates, related to the strength of the U.S. dollar against the NIS, in the three months ended March 31, 2016, compared to the three months ended March 31, 2015.

Net Loss

Net loss for the nine and three month periods ended March 31, 2016 was \$17,041,000 and \$7,203,000, respectively, as compared to net loss of \$19,382,000 and \$7,226,000 for the nine and three month periods ended March 31, 2015, respectively. The changes were due to the increased revenues related to the termination of the United Agreement, as described above. Net loss per share for the nine and three month periods ended March 31, 2016 was \$0.21 and \$0.09, respectively, as compared to \$0.28 and \$0.10 for the nine and three month periods ended March 31, 2015.

For the nine and three month periods ended March 31, 2016 and March 31, 2015, we had weighted average shares of common stock outstanding of 79,350,504, 79,935,477 and 69,954,373, 70,668,008, respectively, which were used in the computations of net loss per share for the nine and three-month periods.

The increase in weighted average common shares outstanding reflects the issuance of additional shares, mainly the issuances of shares related to the offering we closed in June 2015, issuances of shares to employees and consultants, shares issued under a private placement during fiscal year 2015, and shares issued as a result of exercises of warrants and options.

Liquidity and Capital Resources

As of March 31, 2016, our total current assets were \$39,127,000 and total current liabilities were \$4,808,000. On March 31, 2016, we had a working capital surplus of \$34,319,000, stockholders' equity of \$43,106,000 and an accumulated deficit of \$155,552,000. 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, licensing fees and other potential payments under licensing agreements, and funds from grants from the OCS and Israel's Ministry of Economy and other research grants.

Cash and cash equivalents as of March 31, 2016 amounted to \$5,404,000 compared to \$8,944,000 as of March 31, 2015 and compared to \$22,626,000 as of June 30, 2015. Cash balances changed in the nine months ended March 31, 2016 and 2015 for the reasons presented below.

Operating activities used cash of \$12,978,000 in the nine months ended March 31, 2016, compared to \$15,588,000 in the nine months ended March 31, 2015. Cash used in operating activities in the nine months ended March 31, 2016 and 2015 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 by the OCS and Israel's Ministry of Economy. During the nine months ended March 31, 2016, operating activities

were also offset by the participation of MTM – Scientific Industries Center Haifa Ltd., or MTM, in the cost of constructing additional office space, as described below.

Investing activities used cash of \$5,051,000 in the nine months ended March 31, 2016, compared to cash provided of \$18,674,000 for the nine months ended March 31, 2015. The investing activities in the nine months ended March 31, 2016 consisted primarily of the investment of \$3,524,000 in short term deposits, investment of \$3,954,000 in marketable securities and investment of \$1,535,000 in property and equipment. Our investment activities also provided cash of \$3,929,000 from the sale and redemption of marketable securities. The investing activities in the nine months ended March 31, 2015 consisted primarily of the withdrawal of \$12,511,000 of short term deposits, \$10,319,000 provided from the sale and redemption of marketable securities, offset by investment of \$3,528,000 in marketable securities and payments of \$638,000 related to investment in property and equipment.

Financing activities generated cash of \$807,000 during the nine months ended March 31, 2016, compared to \$1,365,000 for the nine months ended March 31, 2015. The cash generated in the nine months ended March 31, 2016 from financing activities is related to proceeds received from shares issued in a private placement in May 2015 as described below, and exercises of warrants and options by shareholders. The cash generated in the nine months ended March 31, 2015 from financing activities is attributable to proceeds of \$1,114,000 from a private placement as described below, and exercises of warrants and options by shareholders and employees.

From October 2014 through May 2015, we issued shares of common stock in private placements to an investor. In October 2014, we issued 200,000 shares of common stock to an investor for aggregate cash consideration of \$528,000. In February 2015, we issued an additional 200,000 shares of common stock to an investor for aggregate cash consideration of \$586,000. In May 2015, we issued an additional 300,000 shares of common stock to an investor for consideration in the amount of \$790,000, which was received from the investor during September 2015.

In February 2015, we entered into an agreement with a contractor for the construction of our new laboratories facility for consideration of approximately NIS 3.3 million (approximately \$841,000). Under the terms of the agreement, we paid part of the NIS 3.3 million consideration using 100,004 restricted shares of common stock of the Company, linked to performance milestones with respect to the new laboratories construction and which serve as a guarantee. These restricted shares were issued in December 2014 and will be released to the contractor upon the successful completion of the construction.

In May 2015, we entered into an addendum to the agreement with the contractor for the design and construction of additional office space renovations in our leased facility for additional consideration of approximately NIS 4 million (approximately \$1,032,000), which is comprised of NIS 3 million (approximately \$774,000) in cash and 90,000 restricted shares, which were issued to the contractor in February 2016 upon the successful completion of the construction by the contractor.

We account for the abovementioned share-based payment awards to the contractor in accordance with ASC 505-50, "Equity based payments to non-employees".

The construction work was initiated in June 2015. On October 30, 2015, the contractor completed the agreed construction milestones. We have issued a total of 190,004 restricted shares to the contractor. As a result, we recognized the fair value of the share-based payments awards, using the fair value of the Company's shares on October 30, 2015, totaling approximately \$302,000 as share-based payment to the contractor in "additional paid-in capital" with a corresponding amount included in "property and equipment, net".

In October 2015, MTM, our landlord, participated in the cost of constructing additional office space for us by contributing an amount of NIS 3,683,000 (approximately \$944,000) toward the cost of construction. Such participation was made pursuant to our lease agreement with MTM, and is recognized by rateably deducting from our monthly rent payment over the rent period.

During the nine months ended March 31, 2016, we received cash of approximately \$2,542,000 from the OCS towards our research and development expenses. According to the OCS 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 OCS grants until 100% of the dollar-linked grants amount plus interest are repaid. In the absence of such sales, no payment is required. Through March 31, 2016, total grants obtained aggregated to approximately \$21,183,000, and total royalties paid amounted to \$166,000.

In May 2016, the Subsidiary received an approval for a NIS 12,700,000 (approximately \$3,300,000) grant from the OCS. Once received, the grant will be used to cover research and development expenses for the period from January

1, 2016 to December 31, 2016. This grant is subject to the same repayment restrictions of royalties as the prior OCS grants.

As of today, the currency of our financial portfolio is mainly in U.S. dollars and we use forward and 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 2015 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 May 9, 2016, we have sold 6,800,000 shares of our common stock and warrants to purchase up to 4,080,000 shares of common stock in a total amount of \$17,000,000 in an offering we closed in June 2015.

Outlook

We have accumulated a deficit of \$155,552,000 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. Our management believes that we may need to raise additional funds before we have cash flow from operations that can materially decrease our dependence on our existing cash and other liquidity resources. We are continually looking for sources of funding, including non-diluting sources such as the OCS grants and other research grants, sales of our common stock or sales of the marketable securities we hold.

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

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 Chief Executive Officer (CEO) and our Chief Financial Officer (CFO) as appropriate to allow timely decisions regarding required disclosures.

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

Changes in Internal Control Over Financial Reporting - There has been no change in our internal control over financial reporting during the third quarter of Fiscal 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors.

Our business faces many risks, a number of which are described under the caption “Risk Factors” in our 2015 Annual Report and in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2015, or the Quarterly Report. The risks so described may not be the only risks we face. Additional risks of which we are not yet aware, or that we currently believe are immaterial, may also materially and adversely impact our business operations or financial results. If any of the events or circumstances described in the risk factors contained in our 2015 Annual Report or in the Quarterly Report occurs, our business, financial condition or results of operations could be adversely impacted and the trading price of our securities could decline. Investors and prospective investors should consider the risks described in our 2015 Annual Report and in the Quarterly Report and the information contained under the heading “Forward - Looking Statements” and elsewhere in this Quarterly Report on Form 10-Q before deciding whether to invest in our securities.

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

In February 2016, we issued 90,000 shares of restricted stock to our building contractor, upon the successful completion of the construction, and 6,667 shares of restricted stock to consultants for services rendered.

The above issuances were exempt under Section 4(a)(2) of the Securities Act or Regulation S promulgated under the Securities Act.

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 March 31, 2016 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, Chief Executive Officer
(Principal Executive Officer)
Date: May 9, 2016

By: /s/ Yaky Yanay
Yaky Yanay, Chief Financial Officer, Chief Operating Officer and President
(Principal Financial Officer and Principal Accounting Officer)
Date: May 9, 2016

10
