

PLURISTEM THERAPEUTICS INC

Form 10-Q

November 06, 2014

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, 2014

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)

011-972-74-7108759
(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,

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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:
70,078,391 shares of common stock issued and outstanding as of October 27, 2014.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

As of September 30, 2014

(Unaudited)

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

As of September 30, 2014

U.S. DOLLARS IN THOUSANDS

(Unaudited)

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PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	Note	September 30, 2014 Unaudited	June 30, 2014
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 5,662	\$ 4,493
Short-term bank deposits		14,494	19,451
Restricted cash and short term bank deposits		5,083	4,914
Marketable securities	3	25,898	29,961
Account receivable from OCS		451	2,263
Other current assets		704	905
Total current assets		52,292	61,987
LONG-TERM ASSETS:			
Long-term deposits and restricted deposits		289	304
Severance pay fund		706	901
Property and equipment, net		10,541	10,823
Other long-term assets		2	8
Total long-term assets		11,538	12,036
Total assets		\$ 63,830	\$ 74,023

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	September 30, 2014 Unaudited	June 30, 2014
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		\$ 2,421	\$ 3,465
Accrued expenses		1,003	915
Deferred revenues		379	379
Advance payment from United Therapeutics		218	247
Other accounts payable		1,964	2,391
Total current liabilities		5,985	7,397
LONG-TERM LIABILITIES			
Deferred revenues		2,752	2,847
Accrued severance pay		832	1,068
Other long-term liabilities		566	588
Total long-term liabilities		4,150	4,503
COMMITMENTS AND CONTINGENCIES	5		
STOCKHOLDERS' EQUITY			
Share capital:	6		
Common stock \$0.00001 par value:			
Authorized: 200,000,000 shares			
Issued and outstanding: 69,585,642 shares as of			
September 30, 2014, 68,601,452 shares as of June 30, 2014		-(*)	-(*)
Additional paid-in capital		174,169	172,998
Accumulated deficit		(119,745)	(113,834)
Other comprehensive income (loss)		(729)	2,959
Total stockholders' equity		53,695	62,123
Total liabilities and stockholders' equity		\$ 63,830	\$ 74,023

(*) 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 OPERATIONS (UNAUDITED)

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

	Three months ended September 30,	
	2014	2013
	Unaudited	Unaudited
Revenues	\$95	\$95
Cost of revenues	(3)	(3)
Gross profit	92	92
Research and development expenses	(5,736)	(5,497)
Less participation by the Office of the Chief Scientist and other parties	1,699	2,374
Research and development expenses, net	(4,037)	(3,123)
General and administrative expenses	(1,678)	(1,829)
Operating loss	(5,623)	(4,860)
Financial income (expense), net	(288)	105
Net loss for the period	\$(5,911)	\$(4,755)
Loss per share:		
Basic and diluted net loss per share	\$(0.09)	\$(0.08)
Weighted average number of shares used in computing basic and diluted net loss per share	69,131,435	59,254,132

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 (except share and per share data)

	Three months ended September 30,	
	2014	2013
Net loss	\$(5,911)	\$(4,755)
Other comprehensive income (loss), net:		
Unrealized loss on derivative instruments	(133)	-
Changes in unrealized gains (losses) on available-for-sale marketable securities, net	(4,010)	537
Reclassification adjustment of available-for-sale marketable securities gains (losses) realized in net loss, net	455	(142)
Other comprehensive income (loss)	(3,688)	395
Total comprehensive loss	\$(9,599)	\$(4,360)

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 and per share data)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Other	Deficit	Stockholders'
			Capital	Income		Equity
Balance as of July 1, 2013	59,196,617	\$(*))	\$144,109	\$ 259	\$ (86,902)	\$ 57,466
Exercise of options and warrants by employees and consultants	5,905	(*)	-	-	-	-
Exercise of warrants by investors and finders	448,082	(*)	509	-	-	509
Stock based compensation to employees, directors and non-employee consultants	202,189	(*)	1,176	-	-	1,176
Other comprehensive income	-	-	-	395	-	395
Net loss	-	-	-	-	(4,755)	(4,755)
Balance as of September 30, 2013	59,852,793	\$(*))	\$145,794	\$ 654	\$ (91,657)	\$ 54,791

(*) 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 and per share data)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Other	Deficit	Stockholders'
			Capital	Comprehensive		Equity
				Income (Loss)		
Balance as of July 1, 2014	68,601,452	\$(*)	\$172,998	\$ 2,959	\$ (113,834)	\$ 62,123
Exercise of options by employees	3,000	(*)	2	-	-	2
Exercise of warrants by investors and finders	534,237	(*)	109	-	-	109
Stock based compensation to employees, directors and non-employee consultants	446,953	(*)	1,060	-	-	1,060
Other comprehensive income (loss), net	-	-	-	(3,688)	-	(3,688)
Net loss	-	-	-	-	(5,911)	(5,911)
Balance as of September 30, 2014	69,585,642	\$(*)	\$174,169	\$ (729)	\$ (119,745)	\$ 53,695

(*) 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 (except share and per share data)

	Three months ended September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(5,911)	\$(4,755)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	498	461
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	44	559
Gain from sale of investments of available-for-sale marketable securities	17	(142)
Stock-based compensation to employees, directors and non-employees consultants	1,060	1,176
Decrease (increase) in OCS receivables	1,812	(2,055)
Decrease (increase) in other accounts receivable	333	(95)
Increase in prepaid expenses	(174)	(7)
Increase (decrease) in trade payables	(989)	247
Increase (decrease) in other accounts payable and accrued expenses	(9)	160
Decrease in deferred revenues	(95)	(474)
Decrease in advance payment from United Therapeutics	(29)	(37)
Increase in interest receivable on short-term deposits	(9)	-
Linkage differences and interest on short and long-term restricted lease deposit	37	(168)
Accrued severance pay, net	(41)	35
Net cash used by operating activities	\$(3,456)	\$(5,095)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	\$(271)	\$(462)
Repayment of short-term deposits	4,777	7,132
Repayment of (Investment in) long-term deposits	1	(3)
Repayment of long-term restricted deposit	-	112
Proceeds from sale of available-for-sale marketable securities	37	1,870
Proceeds from redemption of available-for-sale marketable securities	64	394
Investment in available-for-sale marketable securities	(92)	(4,861)
Net cash provided by investing activities	\$4,516	\$4,182

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 (except share and per share data)

	Three months ended September 30,	
	2014	2013
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of warrants	109	509
Net cash provided by financing activities	\$ 109	\$ 509
Increase (decrease) in cash and cash equivalents	1,169	(404)
Cash and cash equivalents at the beginning of the period	4,493	9,007
Cash and cash equivalents at the end of the period	\$ 5,662	\$ 8,603
(a) Supplemental disclosure of cash flow activities:		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$ 30	\$ 31
(b) Supplemental disclosure of non-cash activities:		
Purchase of property and equipment on credit	\$ 188	\$ 668
Other receivables resulting from exercise of option	\$ 2	\$ -

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 \$119,745 through September 30, 2014 and incurred a net loss of \$5,911 for the three months ended September 30, 2014.

The Company plans to continue to finance its operations with sales of equity securities, entering into licensing technology agreements such as the United Therapeutics Corporation (“United Therapeutics” or “United”) and CHA Bio&Diostech (“CHA”) agreements, 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.

- c. 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”.

- d. License Agreements:

United Agreement

On June 19, 2011, the Company entered into an exclusive license agreement (the “United Agreement”) with United Therapeutics 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 provides that United Therapeutics will 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 provides for the following consideration payable to the Company: (i) an upfront payment of \$7,000 paid in August 2011, which includes 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.

The United Agreement became effective on August 2, 2011, and will continue until the later of a few events, including termination of all patents relating to the collaboration, upon certain government action or if the parties do not develop any product under the United Agreement. United may unilaterally terminate the United Agreement at any time and without cause. In such event, United Therapeutics shall pay the Company certain costs and expenses of winding down any non-cancellable commitments made by the Company prior to the date of termination and cease all development activities in connection with the United Agreement.

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, CHA will bear the costs of conducting the clinical trials for the agreed upon indications, and the Company will continue to retain rights to its proprietary manufacturing technology and cell-related intellectual property.

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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 to be performed as part of the CHA Agreement will be a Phase II trial in Intermittent Claudication. This study was approved in November 2013 by South Korea's Ministry of Food and Drug Safety.

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.

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 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 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.

Each party has agreed to hold the other party's shares for at least one year before selling any of such shares. 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.

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, 2014.

Operating results for the three months period ended September 30, 2014, are not necessarily indicative of the results that may be expected for the year ending June 30, 2015.

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.

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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.)

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.

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.

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.)

Cash Flow Hedges. The Company entered into forward 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 income (expenses), 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. As of September 30, 2014, the Company had forward contracts in place to hedge future payroll and related expenses in NIS of approximately \$2,300, with a fair value of approximately \$123 presented in "other current liabilities". The net unrealized loss on the effective portion of these cash flow hedges was \$133. The net loss realized in statement of operations during the three months ended September 30, 2014, resulting from the cash flow hedge transactions, amounted to approximately \$45. The forward contracts on the Company's future NIS payroll and related expenses will settle by February 2015. On September 30, 2013, the Company did not have any contracts designated and qualified as cash flow hedge.

Fair Value Hedges. The Company entered into forward contracts designated as fair value hedges to hedge foreign currency risks for its investment denominated in currencies other than the U.S. dollar. The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). Gains and losses on these contracts are recognized in "Financial income (expenses), net", along with the offsetting losses and gains of the related hedged items.

In connection with the investment in CHA shares (see Note 1d), an available-for-sale marketable security denominated in Korean Won, the Company entered into a forward contract to hedge against the foreign currency risk between the Korean Won and the U.S. dollar. The notional principal of this contract is \$11,000, with fair value of approximately \$(403) as of September 30, 2014.

The changes in fair value of the available-for-sale CHA shares attributable to the foreign currency risk being hedged are reflected in the statement of operations in "Financial income (expenses), net". Other changes in fair value of the available-for-sale CHA shares continue to follow ASC 320-"Investments-Debt and Equity Securities", accounting and are reflected in other comprehensive income (loss).

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 losses recognized in "Financial income (expenses), net" during the three months ended September 30, 2014, and 2013 were \$198 and \$7, 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:

	3 months ended September 30, 2014 (Unaudited)		
	Unrealized gains on marketable securities	Unrealized gains on cash flow hedges	Total
Balance as of July 1, 2014	\$ 2,936	\$ 23	\$ 2,959
Other comprehensive income (loss) before reclassifications	(4,110)	(178)	(4,288)
Amounts reclassified from accumulated other comprehensive loss	555	45	600
Net current-period other comprehensive income	(3,555)	(133)	3,688
Balance as of September 30, 2014	\$ (619)	\$ (110)	\$ (729)

g. Recent Accounting Pronouncement

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in "Revenue Recognition (Topic 605)", and requires entities to recognize revenue when it transfers 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. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The Company is currently in the process of evaluating the impact of the adoption of ASU 2014-09 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 September 30, 2014, all of the Company's marketable securities were classified as available-for-sale.

	September 30, 2014 (Unaudited)				June 30, 2014			
	Amortized cost	Gross unrealized gain	Gross unrealized loss	Fair value	Amortized cost	Gross unrealized gain	Gross unrealized loss	Fair value
Available-for-sale - matures within one year:								
Stock and index linked notes	\$18,499	\$ 1,006	\$ (1,862)	\$17,643	\$18,881	\$ 2,522	\$ (23)	\$21,380
Government debentures – fixed interest rate	67	4	-	71	97	9	-	106
Corporate debentures – fixed interest rate	790	53	(21)	822	452	54	-	506
	\$19,356	\$ 1,063	\$ (1,883)	\$18,536	\$19,430	\$ 2,585	\$ (23)	\$21,992
Available-for-sale - matures after one year through five years:								
Government debentures – fixed interest rate	2,575	59	(16)	2,618	2,595	98	(1)	2,692
Corporate debentures – fixed interest rate	4,491	155	(9)	4,637	4,906	263	(5)	5,164
	\$7,066	\$ 214	\$ (25)	\$7,255	\$7,501	\$ 361	\$ (6)	\$7,856
Available-for-sale - matures after five years through ten years:								
Corporate debentures – fixed interest rate	95	12	-	107	94	19	-	113
	\$95	\$ 12	\$ -	\$107	\$94	\$ 19	\$ -	\$113
	\$26,517	\$ 1,289	\$ (1,908)	\$25,898	\$27,025	\$ 2,965	\$ (29)	\$29,961

The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of September 30, 2014 and June 30, 2014, 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	Fair Value	Gross

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		unrealized loss		unrealized loss
As of September 30, 2014 (Unaudited)	\$2,336	\$(129) \$452	\$(19)
As of June 30, 2014	\$851	\$(17) \$463	\$(12)

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-month period ended September 30, 2014.

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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

	September 30, 2014 (Unaudited)		June 30, 2014	
	Level 1	Level 2	Level 1	Level 2
	Marketable securities	\$16,512	\$9,386	\$20,530
Foreign currency derivative instruments	-	(701)	-	(842)
Total financial assets	\$16,512	\$8,685	\$20,530	\$8,589

	September 30, 2014 (Unaudited)		June 30, 2014	
	Balance Sheet location	Fair Value	Balance Sheet location	Fair Value
Derivatives designated as a cash flow hedge instruments	Other current liabilities	\$(123)	Other current assets	\$24
Derivatives not designated as hedge instruments	Other current liabilities	(175)	Other current assets	23
Derivatives designated as a fair value hedge instruments	Other current liabilities	(403)	Other current liabilities	(889)
Total		\$(701)		\$(842)

NOTE 5: - COMMITMENTS AND CONTINGENCIES

Commitments and contingencies that changed during the three months ended September 30, 2014, include the following:

- Increase in the amount of \$155 of cash pledged by the Company to secure its hedging transactions, credit line and bank guarantees.
- The Company, through its Israeli subsidiary, participated in programs sponsored by the Israeli Government for the support of research and development activities. The Company is obligated to pay royalties to the OCS, amounting to 3%-4% of the sales of the products and other related revenues generated from such projects, up to 100% of the grants received, linked to the U.S. dollars and for grants received after January 1, 1999, also bearing interest at the rate of LIBOR. The obligation to pay these royalties is contingent on actual revenues and in the absence of such revenues, no payment is required.

Through September 30, 2014, total grants obtained aggregated to approximately \$17,406, and total royalties paid and accrued amounted to \$57. As of September 30, 2014, the Company's contingent liability in respect to royalties to the OCS amounted \$17,349, not include LIBOR interest as described above.

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

a. From July 2014 through September 2014, a total of 949,210 warrants were exercised via “cashless” exercise, resulting in the issuance of 461,570 shares of common stock to investors of the Company. In addition, 72,667 warrants were exercised for cash and resulted in the issuance of 72,667 shares of common stock to investors of the Company. The aggregate cash consideration received was \$109.

b. Following a shelf registration on Form S-3 filed and declared effective in October 2011, the Company entered in December 2012 into an At Market Issuance Sales Agreement (“ATM Agreement”) with an underwriter. On September 11, 2014, the Company notified the underwriter of the termination of the ATM Agreement.

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

1. Options to employees and directors:

A summary of the Company’s share option activity for options granted to employees and directors under the Plans is as follows:

	Three months ended September 30, 2014 (Unaudited)			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	1,862,099	\$ 3.73		
Options exercised	(3,000)	\$ 0.62		
Options forfeited	-			
Options outstanding at end of the period	1,859,099	\$ 3.73	2.87	\$ 929
Options exercisable at the end of the period	1,859,099	\$ 3.73	2.87	\$ 929
Options vested	1,859,099	\$ 3.73	2.87	\$ 929

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, 2014. 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 Company's activity related to options and warrants to consultants is as follows:

During the three month period ended September 30, 2014, there were no grants, exercised or forfeitures of options and warrants to non-employees consultants.

	Three months ended September 30, 2014 (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	252,000	\$ 5.19		
Options and warrants outstanding at end of the period	252,000	\$ 5.19	3.71	\$ 300
Options and warrants exercisable at the end of the period	252,000	\$ 5.19	3.71	\$ 300
Options and warrants vested and expected to vest	252,000	\$ 5.19	3.71	\$ 300

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

	Three months ended September 30,	
	2014 (Unaudited)	2013 (Unaudited)
Research and development expenses	\$ 1	\$ -
General and administrative expenses	-	2
	\$ 1	\$ 2

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:

During the three month period ended September 30, 2014, the Company granted restricted stock units to several of the Company's employees and directors.

The following table summarizes the activities for unvested restricted stock units granted to employees and directors for the three months ended September 30, 2014 (Unaudited):

	Number
Unvested at the beginning of period	1,589,432
Granted	24,499
Forfeited	(8,725)
Vested	(439,078)
Unvested at the end of the period	1,166,128
Expected to vest after September 30, 2014	1,141,828

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

	Three months ended September 30,	
	2014 (Unaudited)	2013 (Unaudited)
Research and development expenses	\$ 333	\$ 126
General and administrative expenses	702	1,048
	\$ 1,035	\$ 1,174

Unamortized compensation expenses related to restricted stock units granted to employees and directors to be recognized of an average time of approximately 2 years is \$1,499.

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 units to consultants:

During the three month period ended September 30, 2014, the Company granted restricted stock units to several consultants and service providers.

The following table summarizes the activities for unvested restricted stock units granted to consultants for the three months ended September 30, 2014:

	Number
Unvested at the beginning of period	15,250
Granted	5,000
Forfeited	-
Vested	(7,875)
Unvested at the end of the period	12,375
Expected to vest after September 30, 2014	12,375

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

	Three months ended September 30,	
	2014 (Unaudited)	2013 (Unaudited)
Research and development expenses	\$ 20	\$ -
General and administrative expenses	4	-
	\$ 24	\$ -

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 exclusive license agreements we entered into with United Therapeutics Corporation (United) and CHA Bio&Diostech (CHA) (United Agreement and CHA Agreement, respectively) and clinical trials to be conducted according to such agreements;
- 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 conclusion of trials;
- achieving regulatory approvals;
- receipt of future funding from the Office of the Chief Scientist of Israel (OCS);
- developing capabilities for new clinical indications of placenta expanded cells (PLX);
- the potential market demand for our 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, 2014. 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 I 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 PLX (PLacental eXpanded) cells function as a platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals, generated by the patient's own body. PLX cells are grown using our proprietary 3D micro-environment technology that 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. 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 methods 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, such as United and CHA. We have built a Good Manufacturing Practices (GMP) grade facility and we are planning to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

RESULTS OF OPERATIONS –THREE MONTHS ENDED SEPTEMBER 30, 2014 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2013

Revenues

Revenues for each of the three months ended September 30, 2014 and for the three months ended September 30, 2013 were \$95,000. All such revenues are derived from the United Agreement. The Company estimated the performance period of the development of approximately 8.25 years as of September 2014. The license fee will be recognized on a straight line basis as revenue over the estimated development period.

Research and Development Expenses, Net

Research and development net costs (costs less participation and grants by the OCS and other parties) for the three months ended September 30, 2014 increased by 29% from \$3,123,000 for the three months ended September 30, 2013 to \$4,037,000. This increase is attributed to the material increase in our in-house research and development activity, increase in our salaries due to, among other things, an increase of 6 employees as compared to the average number of employees in the three months ended September 30, 2013, increase in stock-based compensation expenses related to our employees and decrease in the OCS participation, due to the timing in which the OCS approval was granted.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2014 decreased by 8% from \$1,829,000 for the three months ended September 30, 2013 to \$1,678,000 mainly due to a decrease in stock-based compensation expenses related to our employees, directors and officers, offset by an increase in our salaries due to, among other things, an increase of 4 employees as compared to the average number of employees in the three months ended September 30, 2013.

Financial Expense, Net

Financial expense, net, increased from a net income of \$105,000 for the three months ended September 30, 2013 to a net expense of \$288,000 for the three months ended September 30, 2014 mainly due to an increase in exchange rates expenses and a greater loss from our hedging instruments, related to the strength of the U.S. dollar against the New Israeli Shekel (NIS), in the three months ended September 30, 2014.

Net Loss

Net loss for the three months ended September 30, 2014 was \$5,911,000 as compared to a net loss of \$4,755,000 for the three months ended September 30, 2013. The change was due to the increased expenses, as described above. Net loss per share for the three months ended September 30, 2014 was \$0.09 compared to net loss per share of \$0.08 for the three months ended September 30, 2013.

For the periods ended September 30, 2014 and September 30, 2013, we had weighted average shares of common stock outstanding of 69,131,435 and 59,254,132, 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 the shares issued to CHA in December 2013 and the shares issued under an At Market Issuance Sales Agreement during February, March, and June 2014.

Liquidity and Capital Resources

As of September 30, 2014, our total current assets were \$52,292,000 and total current liabilities were \$5,985,000. On September 30, 2014, we had a working capital surplus of \$46,307,000, stockholders' equity of \$53,695,000 and an accumulated deficit of \$119,745,000. We finance our operations and plan to continue doing so from our existing cash, issuances of our securities, licensing fees and other payments under licensing agreements, and funds from grants from the OCS.

Cash and cash equivalents as of September 30, 2014 amounted to \$5,662,000 compared to \$8,603,000 as of September 30, 2013. Cash balances increased in the three months ended September 30, 2014 for the reasons presented below.

Operating activities used cash of \$3,456,000 in the three months ended September 30, 2014, compared to \$5,095,000 for the three months ended September 30, 2013 consisting 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 an OCS grant.

Investing activities provided cash of \$4,516,000 in the three months ended September 30, 2014, compared to \$4,182,000 for the three months ended September 30, 2013. The investing activities in the three months ended September 30, 2014 consisted primarily of the withdrawal of \$4,777,000 of short term deposits, offset by purchases of property and equipment in the amount of \$271,000. The investing activities in the three months ended September 30, 2013 consisted primarily of the withdrawal of \$7,132,000 of short term deposits, offset by investing \$4,861,000 in marketable securities.

Financing activities generated cash of \$109,000 during the three months ended September 30, 2014, compared to \$509,000 for the three months ended September 30, 2013. The cash generated from financing activities in the three months ended September 30, 2014 and 2013 was from exercises of warrants by shareholders.

From July 2014 through September 2014, a total of 949,210 warrants were exercised via "cashless" exercise, resulting in the issuance of 461,570 shares of common stock to investors. In addition, 72,667 warrants were exercised for cash and resulted in the issuance of 72,667 shares of common stock to investors. The aggregate cash consideration received was \$109,000.

During the three months ended September 30, 2014, we received approximately \$3,281,000 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. During the three months ended September 30, 2014, we paid \$5,692 in royalties to the OCS.

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 Annual Report of Form 10-K filed on September 11, 2014.

We have an effective Form S-3 registration statement, filed under the Securities Act of 1933, as amended (Securities Act) with the Securities and Exchange Commission (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 million.

Outlook

We have accumulated a deficit of \$119,745,000 since our inception in May 2001. We do not expect to generate any revenues from sales of products in the next twelve months. Our products will likely not be ready for sale for at least three years, if at all. 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, as we have in the United Agreement. 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, 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 first quarter of fiscal 2015 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 Chief Executive Officer.

31.2* Rule 13a-14(a) Certification of Chief Financial Officer.

32.1** Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.

32.2** Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.

101 * The following materials from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 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: November 6, 2014

By: /s/ Boaz Gur-Lavie
Boaz Gur-Lavie, Chief Financial Officer and Secretary
(Principal Financial Officer and Principal Accounting Officer)
Date: November 6, 2014

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