

PLURISTEM THERAPEUTICS INC

Form 10-Q

November 05, 2013

---

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, 2013

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)

011-972-74-7107171  
(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

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-Q

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="radio"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="radio"/>	Smaller reporting company	<input type="radio"/>

(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:  
59,883,919 shares of common stock issued and outstanding as of October 29, 2013.

---

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

As of September 30, 2013

(Unaudited)

---

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

As of September 30, 2013

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-18

---

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. Dollars in thousands

	Note	September 30, 2013 Unaudited	June 30, 2013
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents		\$ 8,603	\$ 9,007
Short term bank deposits		24,047	31,449
Restricted cash and restricted short-term deposits		753	316
Marketable securities	3	16,016	13,441
Other current assets		3,049	872
Total current assets		52,468	55,085
<b>LONG-TERM ASSETS:</b>			
Long-term deposits and restricted deposits		311	421
Severance pay fund		1,020	905
Property and equipment, net		11,663	11,866
Other long-term assets		21	39
Total long-term assets		13,015	13,231
Total assets		\$ 65,483	\$ 68,316

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, 2013 Unaudited	June 30, 2013
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
Trade payables		\$ 2,880	\$ 2,837
Accrued expenses		1,003	1,040
Deferred revenues		379	379
Advance payment from United Therapeutics		356	393
Other accounts payable		1,113	1,272
Total current liabilities		5,731	5,921
<b>LONG-TERM LIABILITIES</b>			
Deferred revenues		3,131	3,226
Accrued severance pay		1,173	1,023
Other long-term liabilities		657	680
Total long-term liabilities		4,961	4,929
<b>COMMITMENTS AND CONTINGENCIES</b>	5		
<b>STOCKHOLDERS' EQUITY</b>			
Share capital:	6		
Common stock \$0.00001 par value:			
Authorized: 100,000,000 shares			
Issued and outstanding: 59,852,793 shares as of September 30,			
2013, 59,196,617 shares as of June 30, 2013		-(*)	-(*)
Additional paid-in capital		145,794	144,109
Accumulated deficit		(91,657)	(86,902)
Other comprehensive income		654	259
Total stockholders' equity		54,791	57,466
Total liabilities and stockholders' equity		\$ 65,483	\$ 68,316

(\*) 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,	
	2013	2012
Revenues	\$95	\$195
Cost of revenues	(3	(6
Gross profit	92	189
Operating expenses:		
Research and development expenses	(5,497	(3,748
Less participation by the Office of the Chief Scientist and other parties	2,374	1,050
Research and development expenses, net	(3,123	(2,698
General and administrative expenses	(1,829	(1,681
Total operating expenses	(4,952	(4,379
Operating loss	(4,860	(4,190
Financial income, net	105	195
Net loss	\$(4,755	\$(3,995
Loss per share:		
Basic and diluted net loss per share	\$(0.08	\$(0.08
Weighted average number of shares used in computing basic and diluted net loss per share	59,254,132	47,833,654

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

	Three months ended September 30,	
	2013	2012
Net loss	\$(4,755 )	\$(3,995 )
Other comprehensive income (loss):		
Changes in unrealized gain on available-for-sale marketable securities	537	229
Reclassification adjustment for gains realized in net loss	(142 )	-
Other comprehensive income	395	229
Total comprehensive loss	\$(4,360 )	\$(3,766 )

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 Capital	Other Comprehensive Income (Loss)	Deficit	Stockholders' Equity
Balance as of July 1, 2012	46,448,051	\$(* )	\$103,619	\$ (130 )	\$ (65,747 )	\$ 37,742
Issuance of common stock and warrants related to September 2012 public offering, net of issuance costs of \$2,694	9,200,000	(* )	34,106	-	-	34,106
Exercise of options by employees and consultants	94,332	(* )	146	-	-	146
Exercise of warrants by investors and finders	975,622	(* )	1,229	-	-	1,229
Stock based compensation to employees, directors and non-employee consultants	539,225	(* )	1,336	-	-	1,336
Stock based compensation to contractor	-	-	1,400	-	-	1,400
Other comprehensive income	-	-	-	229	-	229
Net loss	-	-	-	-	(3,995 )	(3,995 )
Balance as of September 30, 2012	57,257,230	\$(* )	\$141,836	\$ 99	\$ (69,742 )	\$ 72,193

(\*) 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		
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 CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Three months ended September 30,	
	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(4,755 )	\$(3,995 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	461	130
Stock-based compensation to employees, directors and non-employee consultants	1,176	1,063
Stock compensation to investor relations consultants	-	273
Increase in other accounts receivable	(2,150 )	(746 )
Increase in prepaid expenses	(7 )	(483 )
Decrease (increase) in trade payables	247	988
Increase in other accounts payable and accrued expenses	160	30
Increase (decrease) in deferred revenues	(474 )	(195 )
Increase (decrease) in advance payment from United Therapeutics	(37 )	(617 )
Linkage differences and Increase (decrease) interest on short and long-term deposit and restricted lease deposit	(168 )	(37 )
Accretion of discount, amortization of premium and changes in accrued interest from marketable securities	559	43
Loss (gain) from sale of investments of available-for-sale marketable securities	(142 )	15
Accrued severance pay, net	35	9
Net cash used in operating activities	\$(5,095 )	\$(3,522 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$(462 )	\$(1,978 )
Repayment of short-term deposits	7,132	-
Repayment (investment) in long-term deposits	(3 )	300
Repayment of long-term restricted deposit	112	3
Proceeds from sale of available-for-sale marketable securities	1,870	313
Proceeds from redemption of available-for-sale marketable securities	394	-
Investment in available-for-sale marketable securities	(4,861 )	(1,248 )
Net cash provided by (used in) investing activities	\$4,182	\$(2,610 )

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

	Three months ended September 30,	
	2013	2012
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Issuance of common stock and warrants, net of issuance costs	\$-	\$34,106
Exercise of options and warrants	509	1,388
Net cash provided by financing activities	\$509	\$35,494
Increase (decrease) in cash and cash equivalents	(404 )	29,362
Cash and cash equivalents at the beginning of the period	9,007	9,389
Cash and cash equivalents at the end of the period	\$8,603	\$38,751
<b>(a) Supplemental disclosure of cash flow activities:</b>		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$31	\$3
<b>(b) Supplemental disclosure of non-cash activities:</b>		
Purchase of property and equipment on credit	\$668	\$78
Stock based compensation to contractor	\$-	\$1,400

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 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 standardized cell therapy products from human placenta for the treatment of multiple disorders. The Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated losses aggregated to \$91,657 through September 30, 2013. 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") and CHA Bio&Diostech ("CHA") agreements, and from grants to support its R&D activity. In the longer term, the Company plans to finance its operations from revenues from sales of products.

c. Clinical hold lift:

In June 2013, the Company received notification from the U.S. Food and Drug Administration ("FDA") that its United States phase II Intermittent Claudication study had been placed on clinical hold due to a serious allergic reaction in a case which required hospitalization. On September 16, 2013, the Company announced that the FDA lifted the clinical hold.

d. License Agreements:

On June 19, 2011, the Subsidiary entered into an exclusive license agreement ("the License Agreement") with United Therapeutics for the use of its PLX cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension ("PAH"). The License 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 License Agreement 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 expenses if the Company establishes a manufacturing facility in North America upon meeting certain status; (iv) reimbursement of certain costs in connection with the development of the product; and (v) following commercialization of the product, royalties and the purchase of commercial supplies of the developed product from the Company at a specified margin over the Company's cost. On August 2, 2011, the License Agreement became effective following the consent of the Office of the Chief Scientist of Israel ("OCS") within the Israeli Ministry of Economy.

On June 26, 2013, the Subsidiary entered into an exclusive license and commercialization agreement (the "CHA Agreement") with CHA Bio&Diostech ("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, at the sole expense of CHA. Commencement of the clinical trials is conditioned upon the receipt of the necessary regulatory approvals. If

Pluristem's products receive regulatory approvals in South Korea for marketing as treatment for the Indications, the parties will form a joint venture in order to sell, distribute and market Pluristem products for treating the Indications in South Korea. The joint venture would be owned equally by CHA and Pluristem. Pluristem would own any and all intellectual property rights to the extent conceived in connection with its products and license such rights to the joint venture.

F - 10

---

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1:-GENERAL (CONT.)

In an event of lifting the clinical hold by the FDA on a study of another indication conducted by Pluristem (see Note 1c), and reaching an agreed upon development plan for conducting the clinical trials, Pluristem has agreed to issue to CHA 2,500,000 shares of its common stock in consideration for the issuance to Pluristem of 1,011,504 common shares of CHA, which reflect total consideration of approximately \$10,000 for such Pluristem shares (based on the average closing price of CHA common shares over the last 30 trading days preceding the date of the agreement). 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.

The CHA Agreement includes non-competition covenants by CHA for a specified period as well as customary termination and indemnification provisions, including in the event the parties do not reach an agreed upon development plan for conducting the clinical trials.

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, 2013.

Operating results for the three months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending June 30, 2014.

b. Fair value of financial instruments:

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, available-for-sale marketable securities, short-term deposits, trade payable and other accounts payable and accrued liabilities, approximate fair value because of their generally short term maturities.

The Company accounts for certain assets and liabilities at fair value under ASC 820, "Fair Value Measurements and Disclosures". 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:

F - 11

---



PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

b.Fair value of financial instruments (cont.)

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets;

Level 2 - Includes other inputs that are directly or indirectly observable in the marketplace, other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets with insufficient volume or infrequent transactions, or other inputs that are observable (model-derived valuations in which significant inputs are observable), or can be derived principally from or corroborated by observable market data; and

Level 3 - Unobservable inputs which are supported by little or no market activity.

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.

Based on the fair value hierarchy, the Company classifies its marketable securities within Level 1 or Level 2. This is because the Company values its marketable securities using quoted market prices or alternative pricing sources and models utilizing market observable inputs. The Company classifies its foreign currency derivative instruments primarily within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments.

c.Derivative financial instruments

The Company's derivatives are not designated as hedging accounting instruments under ASC 815, "Derivatives and Hedging". Those derivatives consist primarily of forward and options contracts the Company uses to hedge the Company's exposures to currencies other than the U.S. dollar. The Company recognized derivative instruments as either assets or liabilities and measures those instruments at fair value. Since the derivative instruments that the Company holds do not meet the definition of hedging instruments under ASC 815, the Company recognizes changes in the fair values in its statement of income in financial income, net, in the same period as the re-measurement gain and loss of the related foreign currency denominated assets and liabilities.

The fair value of the forward and options contracts as of September 30, 2013 and June 30, 2013 were recorded as an asset of \$86 and \$93, respectively.

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 3:- MARKETABLE SECURITIES

As of September 30, 2013, all of the Company's marketable securities were classified as available-for-sale.

	September 30, 2013 (Unaudited)				June 30, 2013			
	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	\$5,624	\$ 361	\$ (62 )	\$5,923	\$4,023	\$ 234	\$ (180 )	\$4,077
Government debentures – fixed interest rate	163	24	(1 )	186	329	21	-	350
Corporate debentures – fixed interest rate	681	42	(6 )	717	508	30	(9 )	529
	\$6,468	\$ 427	\$ (69 )	\$6,826	\$4,860	\$ 285	\$ (189 )	\$4,956
Available-for-sale - matures after one year through five years:								
Government debentures – fixed interest rate	2,387	60	(5 )	2,442	1,602	49	(12 )	1,639
Corporate debentures – fixed interest rate	5,069	235	(44 )	5,260	4,976	162	(77 )	5,061
	\$7,456	\$ 295	\$ (49 )	\$7,702	\$6,578	\$ 211	\$ (89 )	\$6,700
Available-for-sale - matures after five years through ten years:								
Government debentures – fixed interest rate	\$621	\$ 30	\$ (9 )	\$642	\$955	\$ 45	\$ (14 )	\$986
Corporate debentures – fixed interest rate	817	39	(10 )	846	789	29	(19 )	799
	\$1,438	\$ 69	\$ (19 )	\$1,488	\$1,744	\$ 74	\$ (33 )	\$1,785
	\$15,362	\$ 791	\$ (137 )	\$16,016	\$13,182	\$ 570	\$ (311 )	\$13,441

The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of September 30, 2013 and June 30, 2013, 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	
	Fair Value	Gross unrealized loss	Fair Value	Gross unrealized loss
As of September 30, 2013 (Unaudited)	\$ 4,123	\$ (131 )	\$ 21	\$ (6 )
As of June 30, 2013	\$ 5,122	\$ (302 )	\$ 32	\$ (9 )

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 months ended September 30, 2013.

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

	September 30, 2013 (Unaudited)		June 30, 2013	
	Level 1	Level 2	Level 1	Level 2
Marketable securities	\$ 6,238	\$ 9,778	\$ 6,311	\$ 7,130
Derivatives	-	86	-	93
Total	\$ 6,238	\$ 9,864	\$ 6,311	\$ 7,223

## NOTE 5: - COMMITMENTS AND CONTINGENCIES

Commitments and contingencies that changed during the three months ended September 30, 2013 include the following:

Increase in the amount of \$325 of cash pledged by the Company to secure its hedging transactions, credit line and bank guarantees.

## NOTE 6: - STOCKHOLDERS' EQUITY

From July 2013 through September 2013, a total of 457,000 warrants were exercised via "cashless" exercise, resulting in the issuance of 169,082 shares of common stock to investors of the Company. In addition, 279,000 warrants were exercised for cash and resulted in the issuance of 279,000 shares of common stock to investors of the Company. The aggregate cash consideration received was \$509. In addition, in August 2013, a total of 15,000 warrants were exercised via a "cashless" exercise, resulting in the issuance of 5,905 shares of common stock to a consultant of the Company.

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

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

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

1. Options to employees and directors:

The Company has approved two incentive option plans from 2003 and from 2005 (the "2003 Plan" and the "2005 Plan", and collectively, the "Plans").

The Company accounted 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 share option activity for options granted to employees and directors under the Plans is as follows:

	Three months ended September 30, 2013 (Unaudited)			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	1,958,156	\$ 4.01		
Options forfeited	(50,000 )	\$ 15.31		
Options outstanding at end of the period	1,908,156	\$ 3.73	3.82	\$ 1,195
Options exercisable at the end of the period	1,908,156	\$ 3.73	3.82	\$ 1,195
Options vested	1,908,156	\$ 3.73	3.82	\$ 1,195

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, 2013. 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 per share amounts)

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

a. Options, warrants, restricted stock 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:

	Three months ended September 30, 2013 (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	315,500	\$ 4.40		
Options and warrants exercised	(15,000 )	1.91		
Options and warrants outstanding at end of the period	300,500	\$ 4.56	3.97	\$ 463
Options and warrants exercisable at the end of the period	299,000	\$ 4.59	3.95	\$ 458
Options and warrants vested and expected to vest	300,500	\$ 4.56	3.97	\$ 463

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

	Three months ended September 30,	
	2013	2012
	Unaudited	
Research and development expenses	\$ -	\$ -
General and administrative expenses	2	18
	\$ 2	\$ 18

Future expenses related to options and warrants granted to consultants for an average time of approximately three months is \$1.

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

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

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

3. Restricted stock and restricted stock units to employees and directors:

During the three months ended September 30, 2013, the Company did not grant restricted stock units to any 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, 2013 (Unaudited):

	Number
Unvested at the beginning of period	1,660,525
Granted	-
Forfeited	(20,873 )
Vested	(202,189 )
Unvested at the end of the period	1,437,463
Expected to vest after September 30, 2013	1,420,189

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

	Three months ended September 30, 2013                      2012 Unaudited	
Research and development expenses	\$ 126	\$ 317
General and administrative expenses	1,048	608
	\$ 1,174	\$ 925

Future expenses related to restricted stock and restricted stock units granted to employees and directors for an average time of approximately 1.75 years is \$2,586.

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

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

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

4. Restricted stock and restricted stock units to consultants:

During the three months ended September 30, 2013, the Company did not grant any restricted stock units to consultants and service providers.

During the three months ended September 30, 2013, no restricted stock units held by consultants and service providers were forfeited or vested.

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

	Three months ended September 30, 2013                      2012 Unaudited	
Research and development expenses	\$ -	\$ 120
General and administrative expenses	-	273
	\$ -	\$ 393



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

Forward - Looking Statements

This quarterly report on Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws, and is subject to the safe-harbor created by such Act and laws. Forward-looking statements may include statements regarding our goals, beliefs, strategies, objectives, plans, including product and technology developments, future financial conditions, results or projections or current expectations. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such 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;
- achieving regulatory approvals;
- consummation of comparability study for our new manufacturing facility;
- developing capabilities for new clinical indications of placenta expanded cells (PLX);
- the potential market demand for our products;
- the implications of the clinical hold notification provided by the U.S. Food and Drug Administration (FDA) in June 2013 (Clinical Hold), which has been lifted since then;
- 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. 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

Edgar Filing: PLURISTEM THERAPEUTICS INC - Form 10-Q

Annual Report on Form 10-K for the fiscal year ended June 30, 2013. 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.

3

---

## Overview

We are a bio-therapeutics company developing standardized cell therapy products for the treatment of a variety of local and systemic diseases. Our patented PLX (PLacental eXpanded) cells function as a drug delivery platform that releases a number of therapeutic proteins in response to various local and systemic inflammatory and ischemic signals generated by the patient. PLX cells are grown using our proprietary 3D micro-environment technology that produces an “off-the-shelf” product that requires no tissue matching prior to administration.

We were incorporated as a Nevada corporation in 2001. We have a wholly owned research and development subsidiary in Israel called Pluristem Ltd. We operate in one segment, namely, the research, development and commercialization 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. 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 our own Good Manufacturing Practices facility and we are planning to have in-house production capacity to grow clinical grade PLX cells in commercial quantities and to control all of our proprietary manufacturing processes.

## RESULTS OF OPERATIONS –THREE MONTHS ENDED SEPTEMBER 30, 2013 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2012.

### Revenues

Revenues for the three months ended September 30, 2013 were \$95,000 as compared to revenues \$195,000 for three months ended September 30, 2012. All such revenues are derived from the United Agreement.

This reduction is a result of re-evaluation we did for the development period under the United Agreement. In June 2013, we received notification from the FDA that our United States phase II Intermittent Claudication study had been placed on Clinical Hold due to a serious allergic reaction in a case which required hospitalization. In September 2013, the FDA lifted the Clinical Hold. In June 2013, following the Clinical Hold, we extended the development period for which we received funds from United from 6.5 years to 11.5 years. The license fee will be recognized on a straight line basis as revenue over the estimated development period.

### Research and Development net

Research and development net costs (costs less participation and grants by the OCS and other parties), for the three months ended September 30, 2013 increased in 16% from \$2,698,000 for the three months ended September 30, 2012 to \$3,123,000. This increase is attributed to the material increase in our in-house research and development activity, the increase in expenses related to the clinical trials, increase in our salaries due to, among other things, an increase of 51 employees as compared to the number of employees in September 2012 and increase in our depreciation expenses. This increase was offset by an increase in the participation of the OCS this quarter which is \$2,374,000 compared to the first quarter of fiscal 2012, which was \$1,050,000, due to a delay in approving the 2013 OCS grant. Since the approval for the calendar year 2013 grant was received only in August 2013, we recognized in the quarter ended September 30, 2013 the OCS participation for the nine months ended September 30, 2013.

### General and Administrative

General and administrative expenses for the three months ended September 30, 2013 increased by 9% from \$1,681,000 for the three months ended September 30, 2012 to \$1,829,000 mainly due to an increase in stock-based compensation expenses related to our employees, directors and officers, offset by a decrease in stock-based compensation expenses to investor relations consultants.

#### Financial Income, net

Financial income decreased from \$195,000 for the three months ended September 30, 2012 to \$105,000 for the three months ended September 30, 2013 mainly due to a decrease in gains from hedging instruments, as well as lower interest income on bank deposits, offset by changes in exchange rates.

#### Net Loss

Net loss for the three months ended September 30, 2013 was \$4,755,000 as compared to a net loss of \$3,995,000 for the three months ended September 30, 2012. The change was due to the decrease in revenues and increased expenses described above. Net loss per share for the three months ended September 30, 2013 and for the three months ended September 30, 2012 was \$0.08.

For the periods ended September 30, 2013 and September 30, 2012, we had weighted average shares of common stock outstanding of 59,254,132 and 47,833,654, respectively, that were used in the computations of net loss per share for the three months. The increase in weighted average common shares outstanding reflects shares issued as part of our public offering of our common stock consummated in September 2012 and to a lesser degree a result of exercise of warrants and options and issuance of restricted stock units to employees and consultants.

#### Liquidity and Capital Resources

As of September 30, 2013, our total current assets were \$52,468,000 and total current liabilities were \$5,731,000. On September 30, 2013, we had a working capital surplus of \$46,737,000, stockholders' equity of \$54,791,000 and an accumulated deficit of \$91,657,000. We finance our operations and plan to continue doing so from our existing cash, licensing agreements, funds from grants from the OCS and issuances of our securities.

Cash and cash equivalents as of September 30, 2013 amounted to \$8,603,000 compared to \$9,007,000 as of June 30, 2013, and compared to \$38,751,000 as of September 30, 2012. Cash balances decreased in the three months ended September 30, 2013 for the reasons presented below.

Operating activities used cash of \$5,095,000 in the three months ended September 30, 2013, compared to \$3,522,000 for the three months ended September 30, 2012. Cash used in operating activities in the three months ended September 30, 2013 primarily consisted of payments of salaries to our employees, and payments of fees to our consultants, subcontractors and professional services providers including costs of clinical studies offset by an OCS grant. The cash used in the three months ended September 30, 2012 primarily consisted of payments of salaries to our employees, and payments of fees to our consultants, subcontractors and professional services providers including costs of clinical studies offset by an OCS grant.

Investing activities provided cash of \$4,182,000 in the three months ended September 30, 2013, compared to cash used of \$2,610,000 for the three months ended September 30, 2012. The investing activities in the three months ended September 30, 2013 consisted primarily of withdrawal of \$7,132,000 of short term deposits, offset by investing \$4,861,000 in marketable securities. The investing activities in the three months ended September 30, 2012 consisted primarily of investing \$1,248,000 in marketable securities and purchasing equipment and paying for the construction of our new facilities in the amount of \$1,978,000.

Financing activities generated cash of \$509,000 during the three months ended September 30, 2013, compared to \$35,494,000 for the three months ended September 30, 2012. The cash generated in the three months ended September 30, 2013 from financing activities is from exercises of warrants by shareholders. The cash generated in the three months ended September 30, 2012 from financing activities is attributable to the proceeds from a public offering

of our common stock.

During the past three months, 279,000 warrants were exercised in consideration for \$509,000 in cash, and an additional 472,000 warrants were exercised on a cashless basis resulting in the net issuance of 174,987 shares of stock.

During the three months ended September 30, 2013, we received approximately \$307,000 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% - 5% 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, 2013 we paid \$8,625 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 on Form 10-K filed on September 11, 2013.

#### Outlook

We have accumulated a deficit of \$91,657,000 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.

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, or CEO, and our Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

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

Changes in Internal Control Over Financial Reporting - There has been no change in our internal control over financial reporting during the first quarter of fiscal 2014 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, 2013 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Statements of Changes in Equity, (v) the Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.

\*Filed herewith.

\*\* Furnished herewith.

SIGNATURES

In accordance with the requirements of the Exchange Act, 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 5, 2013

By: /s/ Yaky Yanay  
Yaky Yanay, Executive Vice President, Chief Financial Officer and Secretary  
(Principal Financial Officer and Principal Accounting Officer)  
Date: November 5, 2013

9

---

---