

PLURISTEM THERAPEUTICS INC

Form 10-Q

November 07, 2016

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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, 2016

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-31392

PLURISTEM THERAPEUTICS INC.  
(Exact name of registrant as specified in its charter)

Nevada 98-0351734  
(State or other jurisdiction of incorporation or organization) (IRS Employer Identification No.)

MATAM Advanced Technology Park, Building No. 5, Haifa, Israel 31905  
(Address of principal executive offices)

011-972-74-7108607  
(Registrant's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

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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: 81,020,086 shares of common stock issued and outstanding as of November 2, 2016.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of September 30, 2016

(Unaudited)

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

As of September 30, 2016

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)

|  | September<br>30, 2016 | June 30,<br>2016 |
|--|-----------------------|------------------|
|  | Note                  | Unaudited        |
| <b>ASSETS</b>  |                       |                  |
| <b>CURRENT ASSETS:</b>   |                       |                  |
| Cash and cash equivalents  | \$ 6,098              | \$6,223          |
| Short-term bank deposits   | 6,731                 | 8,570            |
| Restricted cash and short-term bank deposits                     | 543                   | 542              |
| Marketable securities  | 3 15,933              | 17,415           |
| Accounts receivable from the Israel Innovation Authority ("IIA") | 459                   | 2,228            |
| Other current assets   | 550                   | 618              |
| <u>Total</u> current assets                                      | 30,314                | 35,596           |
| <b>LONG-TERM ASSETS:</b>   |                       |                  |
| Long-term deposits and restricted bank deposits                  | 374                   | 363              |
| Severance pay fund   | 748                   | 766              |
| Property and equipment, net                                      | 8,773                 | 9,216            |
| <u>Total</u> long-term assets                                    | 9,895                 | 10,345           |
| <u>Total</u> assets  | \$ 40,209             | \$45,941         |

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

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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)

|  | September<br>30, 2016 | June 30,<br>2016 |
|--|-----------------------|------------------|
|  | Note                  | Unaudited        |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                    |                       |                  |
| <b>CURRENT LIABILITIES</b>   |                       |                  |
| Trade payables   | \$2,288               | \$2,705          |
| Accrued expenses   | 1,513                 | 1,369            |
| Other accounts payable   | 1,573                 | 1,701            |
| Total current liabilities  | 5,374                 | 5,775            |
| <b>LONG-TERM LIABILITIES</b>   |                       |                  |
| Accrued severance pay  | 892                   | 910              |
| Other long-term liabilities  | 1,040                 | 1,100            |
| <u>Total</u> long-term liabilities   | 1,932                 | 2,010            |
| <b>COMMITMENTS AND CONTINGENCIES</b>   | 5                     |                  |
| <b>STOCKHOLDERS' EQUITY</b>  |                       |                  |
| Share capital:   | 6                     |                  |
| Common stock \$0.00001 par value per share:                                    |                       |                  |
| Authorized: 200,000,000 shares   |                       |                  |
| Issued and outstanding: 80,780,201 shares as of September 30, 2016, 80,268,999 |                       |                  |
| shares as of June 30, 2016   | 1                     | 1                |
| Additional paid-in capital   | 198,921               | 198,432          |
| Accumulated deficit  | (168,081)             | (161,757)        |
| Other comprehensive income   | 2,062                 | 1,480            |
| <u>Total</u> stockholders' equity  | 32,903                | 38,156           |
| <u>Total</u> liabilities and stockholders' equity                              | \$40,209              | \$45,941         |

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<br>September 30, |            |
|---|------|-------------------------------------|------------|
|   |      | 2016                                | 2015       |
|   | Note |                                     |            |
| Revenues  | 1c   | -                                   | \$95       |
| Cost of revenues  |      | -                                   | (3 )       |
| Gross profit  |      | -                                   | 92         |
| Research and development expenses   |      | (6,031 )                            | (5,059 )   |
| Less: participation by the IIA and other parties  |      | 1,033                               | 931        |
| Research and development expenses, net  |      | (4,998 )                            | (4,128 )   |
| General and administrative expenses   |      | (1,564 )                            | (1,487 )   |
| Operating loss  |      | (6,562 )                            | (5,523 )   |
| Financial income (expense), net   |      | 238                                 | (353 )     |
| Net loss  |      | \$(6,324 )                          | \$(5,876 ) |
| Loss per share:   |      |                                     |            |
| Basic and diluted net loss per share  |      | \$(0.08 )                           | \$(0.07 )  |
| Weighted average number of shares used in computing basic<br>and diluted net loss per share |      | 80,674,961                          | 78,704,746 |

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<br>ended September<br>30, |           |
|--|--|-----------|
|  | 2016                                   | 2015      |
| Net loss   | \$(6,324)                              | \$(5,876) |
| Other comprehensive income (loss), net:  |  |           |
| Unrealized gain (loss) on derivative instruments   | -                                      | (39 )     |
| Unrealized gain (loss) on available-for-sale marketable securities, net  | 586                                    | (1,771)   |
| Reclassification adjustment of derivative instruments gains (losses) realized in net loss, net                   | -                                      | (7 )      |
| Reclassification adjustment of available-for-sale marketable securities gains (losses) realized in net loss, net | (4 )                                   | 119       |
| Other comprehensive income (loss)  | 582                                    | (1,698)   |
| Total comprehensive loss   | \$(5,742)                              | \$(7,574) |

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

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## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

|   | Common Stock |        | Additional<br>Paid-in | Receivable<br>on<br>account<br>of shares | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|---|--------------|--------|-----------------------|--|---|------------------------|----------------------------------|
|   | Shares       | Amount | Capital               |  |   |                        |                                  |
| Balance as of July 1, 2015  | 78,771,905   | \$ 1   | \$ 195,303            | \$ (790 )                                | \$ 2,140  | \$ (138,511 )          | \$ 58,143                        |
| Exercise of options by<br>employees and non-employee<br>consultants                 | 25,000       | (* )   | 16                    | -  | -   | -                      | 16                               |
| Stock-based compensation to<br>employees, directors and<br>non-employee consultants | 401,348      | (* )   | 908                   | -  | -   | -                      | 908                              |
| Proceeds related to issuance of<br>common stock in a private<br>placement (Note 6a) | -            | -      | -                     | 790                                      | -   | -                      | 790                              |
| Stock-based compensation to<br>contractor (Note 6b)                                 | -            | -      | 65                    | -  | -   | -                      | 65                               |
| Other comprehensive loss, net   | -            | -      | -                     | -  | (1,698 )  | -                      | (1,698 )                         |
| Net loss  | -            | -      | -                     | -  | -   | (5,876 )               | (5,876 )                         |
| Balance as of September 30,<br>2015 (unaudited)                                     | 79,198,253   | \$ 1   | \$ 196,292            | \$ -                                     | \$ 442  | \$ (144,387 )          | \$ 52,348                        |

(\*) Less than \$1

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

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## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

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

(\*) Less than \$1

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

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## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

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

U.S. Dollars in thousands

|   | Three months<br>ended September<br>30, |           |
|---|--|-----------|
|   | 2016                                   | 2015      |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |  |           |
| Net loss  | \$(6,324)                              | \$(5,876) |
| Adjustments to reconcile net loss to net cash used in operating activities:                             |  |           |
| Depreciation  | 558                                    | 497       |
| Gain from sale of property and equipment, net   | (4 )                                   | (3 )      |
| Accretion of discount, amortization of premium and changes in accrued interest of marketable securities | (33 )                                  | 136       |
| Gain from sale of investments of available-for-sale marketable securities                               | (4 )                                   | (17 )     |
| Stock-based compensation to employees, directors and non-employees consultants                          | 485                                    | 908       |
| Decrease in Accounts receivable from the IIA  | 1,769                                  | 1,272     |
| Decrease in other current assets  | 68                                     | 863       |
| Decrease in trade payables  | (389 )                                 | (1,326)   |
| Decrease in other accounts payable, accrued expenses and other long-term liabilities                    | (44 )                                  | (165 )    |
| Decrease in deferred revenues   | -                                      | (95 )     |
| Decrease in advance payment from United   | -                                      | (23 )     |
| Decrease (increase) in interest receivable on short-term deposits                                       | (2 )                                   | 35        |
| Linkage differences and interest on short and long-term deposits and restricted bank deposits           | (3 )                                   | 24        |
| Accrued severance pay, net  | -                                      | 2         |
| Net cash used by operating activities   | \$(3,923)                              | \$(3,768) |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |  |           |
| Purchase of property and equipment  | \$(145 )                               | \$(1,106) |
| Proceeds from sale of property and equipment  | 6                                      | 3         |
| Repayment of (investment in) short-term deposits  | 1,834                                  | (7,928)   |
| Repayment of (investment in) long-term deposits and restricted bank deposits                            | (2 )                                   | 2         |
| Proceeds from sale of available-for-sale marketable securities  | 2,732                                  | 517       |
| Proceeds from redemption of available-for-sale marketable securities                                    | 55                                     | 229       |
| Investment in available-for-sale marketable securities  | (686 )                                 | (576 )    |
| Net cash provided by (used in) investing activities   | \$3,794                                | \$(8,859) |

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<br>ended September<br>30, |          |
|--|--|----------|
|  | 2016                                   | 2015     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                     |  |          |
| Proceeds related to issuance of common stock and warrants, net of issuance costs | -                                      | \$790    |
| Exercise of options  | 4                                      | 16       |
| Net cash provided by financing activities  | \$4                                    | \$806    |
| Decrease in cash and cash equivalents  | (125 )                                 | (11,821) |
| Cash and cash equivalents at the beginning of the period                         | 6,223                                  | 22,626   |
| Cash and cash equivalents at the end of the period                               | \$6,098                                | \$10,805 |
| <b>(a) Supplemental disclosure of cash flow activities:</b>                      |  |          |
| Cash paid during the period for:   |  |          |
| Taxes paid due to non-deductible expenses  | \$8                                    | \$8      |
| <b>(b) Supplemental disclosure of non-cash activities:</b>                       |  |          |
| Purchase of property and equipment on credit                                     | \$98                                   | \$165    |
| Share consideration to contractor  | \$-                                    | \$65     |

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

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

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

b. The Company is a bio-therapeutics company developing placenta-based cell therapy product candidates for the treatment of multiple ischemic and inflammatory conditions. The Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated losses aggregated to \$168,081 through September 30, 2016, and the Company incurred a net loss of \$6,324 for the three month period ended September 30, 2016.

As of September 30, 2016, the Company's cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$28,762. The Company plans to continue to finance its operations with sales of equity securities, entering into licensing technology agreements (see Note 1c) and from grants to support its research and development activity. Management believes that these funds, together with its existing operating plan, are sufficient for the Company to meet its obligations as they come due at least for a period of twelve months from the date of the interim condensed consolidated financial statements. In the longer term, the Company plans to finance its operations from revenues from sales of products.

c. License Agreements:

United Therapeutics Corporation ("United") Agreement

On June 19, 2011, the Company entered into an exclusive license agreement (the "United Agreement") with United for the use of the Company's PLX cells to develop and commercialize a cell-based product for the treatment of Pulmonary Hypertension ("PAH"). The United Agreement provided that United would receive exclusive worldwide license rights for the development and commercialization of the Company's PLX cell-based product to treat PAH.

Under the United Agreement, the Company received an upfront payment of \$7,000 paid in August 2011, which included a \$5,000 non-refundable upfront payment and a \$2,000 advance payment on development.

On December 8, 2015, the Company received a notice from United terminating the United Agreement, effective immediately. Pursuant to the United Agreement termination clause, Pluristem regained full rights to PLX in the field of PAH, as well as all clinical data and regulatory submissions. As the Company has no further obligations towards United, the Company recognized the remaining upfront payment received in August 2011 as revenues during the year ended June 30, 2016.

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

On June 26, 2013, Pluristem entered into an exclusive license and commercialization agreement (the "CHA Agreement") with CHA, for conducting clinical trials and commercialization of Pluristem's PLX-PAD product in South Korea in connection with two indications: the treatment of Critical Limb Ischemia and Intermittent Claudication (the

“Indications”). Under the terms of the CHA Agreement, CHA will receive exclusive rights in South Korea for conducting clinical trials with respect to the Indications, and the Company will continue to retain rights to its proprietary manufacturing technology and cell-related intellectual property.

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

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

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

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

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

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

The remaining investment in CHA shares is presented as "Marketable Securities" and classified as available-for-sale in accordance with Accounting Standards Codification (the "ASC") 320, "Investments - Debt and Equity Securities". The fair value of the remaining investment as of September 30, 2016 is \$5,717.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

a. Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of U.S. Securities and Exchange Commission Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation have been included (consisting only of normal recurring adjustments except as otherwise discussed).

For further information, reference is made to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2016.

Operating results for the three month period ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending June 30, 2017.

b. Significant Accounting Policies

The significant accounting policies followed in the preparation of these unaudited interim condensed consolidated financial statements are identical to those applied in the preparation of the latest annual financial statements.

c. Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates, judgments and assumptions that are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. Fair value of financial instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, short-term and restricted bank deposits, 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". 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.





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 (CONT.)

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company categorized each of its fair value measurements in one of these three levels of hierarchy (see Note 4).

e. Derivative financial instruments

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

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

**Cash Flow Hedges.** The Company entered into forward and option contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses denominated in New Israeli Shekels (“NIS”). The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2). The gain or loss on the effective portion of a cash flow hedge is initially reported as a component of accumulated other comprehensive income and subsequently reclassified into operating expenses in the same period or periods in which the payroll and related expenses are recognized, or reclassified into “Financial 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.

**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 fair value of approximately \$130 presented in “other current assets” and the net gains (losses) recognized in “Financial income (expense), net” during the three month periods ended September 30, 2016 and 2015, were \$65 and (\$285), respectively.

f. Recent Accounting Pronouncement

Accounting Standards Update (“ASU”) 2014-09 - Revenue from Contracts with Customers (Topic 606):

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a

five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances.

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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 (CONT.)

## f. Recent Accounting Pronouncement (con.):

The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. In April 2016, the FASB issued ASU 2016-10, which clarifies the implementation guidance on identifying promised goods or services and on determining whether an entity's promise to grant a license with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The guidance is effective for the interim and annual periods beginning on or after December 15, 2017, or July 1, 2018 for the Company (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The guidance permits the use of either a retrospective or cumulative effect transition method. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

## NOTE 3:- MARKETABLE SECURITIES

As of September 30, 2016, all of the Company's marketable securities were classified as available-for-sale.

|  | September 30, 2016 (Unaudited) |                       |                       |            | June 30, 2016  |                       |                       |                                 |                 |
|--|--------------------------------|-----------------------|-----------------------|------------|----------------|-----------------------|-----------------------|---------------------------------|-----------------|
|  | Amortized cost                 | Gross unrealized gain | Gross unrealized loss | Fair Value | Amortized cost | Gross unrealized gain | Gross unrealized loss | Other-than-temporary impairment | Temporary value |
| Available-for-sale - matures within one year:                    |                                |                       |                       |            |                |                       |                       |                                 |                 |
| Stock and index linked notes                                     | \$11,507                       | \$2,110               | \$(103)               | \$13,514   | \$11,599       | \$1,594               | \$(208)               | \$(38)                          | \$12,947        |
| Government debentures – fixed interest rate                      | 101                            | 2                     | -                     | 103        | 786            | 12                    | -                     | -                               | 798             |
| Corporate debentures – fixed interest rate                       | -                              | -                     | -                     | -          | 439            | 7                     | -                     | -                               | 446             |
|  | \$11,608                       | \$2,112               | \$(103)               | \$13,617   | \$12,824       | \$1,613               | \$(208)               | \$(38)                          | \$14,191        |
| Available-for-sale - matures after one year through five years:  |                                |                       |                       |            |                |                       |                       |                                 |                 |
| Government debentures – fixed interest rate                      | 620                            | 25                    | -                     | 645        | 717            | 27                    | -                     | -                               | 744             |
| Corporate debentures – fixed interest rate                       | 1,627                          | 28                    | -                     | 1,655      | 2,403          | 47                    | -                     | -                               | 2,450           |
|  | \$2,247                        | \$53                  | \$-                   | \$2,300    | \$3,120        | \$74                  | \$-                   | \$-                             | \$3,194         |
| Available-for-sale - matures after five years through ten years: |                                |                       |                       |            |                |                       |                       |                                 |                 |
| Corporate debentures – fixed interest rate                       | 16                             | -                     | -                     | 16         | 29             | 1                     | -                     | -                               | 30              |
|  | \$16                           | \$-                   | \$-                   | \$16       | \$29           | \$1                   | \$-                   | \$-                             | \$30            |

\$13,871 \$2,165 \$(103 ) \$15,933 \$15,973 \$1,688 \$(208 ) \$ (38 ) \$17,415

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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 3:- MARKETABLE SECURITIES (CONT.)

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

|                                      | Less than 12 months |                       | 12 months or greater |                       |
|--------------------------------------|---------------------|-----------------------|----------------------|-----------------------|
|                                      | Fair Value          | Gross unrealized loss | Fair Value           | Gross unrealized loss |
| As of September 30, 2016 (Unaudited) | \$1,364             | \$ (79 )              | \$201                | \$ (25 )              |
| As of June 30, 2016                  | \$1,258             | \$ (143 )             | \$563                | \$ (65 )              |

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, 2016.

## NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

|   | September 30, 2016<br>(Unaudited) |         | June 30, 2016 |         |
|---|-----------------------------------|---------|---------------|---------|
|   | Level 1                           | Level 2 | Level 1       | Level 2 |
| Marketable securities                   | \$11,203                          | \$4,730 | \$11,228      | \$6,187 |
| Foreign currency derivative instruments | -                                 | 130     | -             | 65      |
| Total financial assets                  | \$11,203                          | \$4,860 | \$11,228      | \$6,252 |

|   | September 30, 2016 (Unaudited)<br>Balance Sheet presentation |            | June 30, 2016<br>Balance Sheet presentation |            | Fair Value |
|---|--|------------|---|------------|------------|
|   | Other current assets   | Fair Value | Other current assets                        | Fair Value |            |
| Derivatives not designated as hedge instruments |  | \$ 130     |   | \$ 65      |            |
| Total   |  | \$ 130     |   | \$ 65      |            |

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 5: - COMMITMENTS AND CONTINGENCIES

a. An amount of \$543 of cash and deposits was pledged by the Subsidiary to secure the derivatives and hedging transactions, credit line and bank guarantees.

b. Under the Law for the Encouragement of Industrial Research and Development, 1984, (the "Research Law"), research and development programs that meet specified criteria and are approved by the IIA are eligible for grants of up to 50% of the project's expenditures, as determined by the research committee, in exchange for the payment of royalties from the sale of products developed under the program. Regulations under the Research Law generally provide for the payment of royalties to the IIA of 3% to 4% on sales of products and services derived from a technology developed using these grants until 100% of the dollar-linked grant is repaid. The Company's obligation to pay these royalties is contingent on its actual sale of such products and services. In the absence of such sales, no payment is required. Outstanding balance of the grants will be subject to interest at a rate equal to the 12 month LIBOR applicable to dollar deposits that is published on the first business day of each calendar year. Following the full repayment of the grant, there is no further liability for royalties.

Through September 30, 2016, total grants obtained aggregated to approximately \$24,018 and total royalties paid and accrued amounted to \$166. As of September 30, 2016, the Company's contingent liability in respect to royalties to the IIA amounted \$23,852, not including LIBOR interest as described above.

NOTE 6: - STOCKHOLDERS' EQUITY

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

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

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

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

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

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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 6: - STOCKHOLDERS' EQUITY (CONT.)

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

## 1. Options to employees and directors:

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

|  | Three months ended September 30, 2016<br>(Unaudited) |  |  |  |
|--|--|--|--|--|
|  | Number   | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Terms (in<br>years) | Aggregate<br>Intrinsic<br>Value<br>Price |
| Options outstanding at beginning of period   | 1,771,700  | \$ 3.759                                 |  |  |
| Options forfeited                            | (12,500 )  | \$ 4.00                                  |  |  |
| Options exercised                            | (6,000 )   | \$ 0.62                                  |  |  |
| Options outstanding at end of the period     | 1,753,200  | \$ 3.768                                 | 0.906  | \$ 357                                   |
| Options exercisable at the end of the period | 1,753,200  | \$ 3.768                                 | 0.906  | \$ 357                                   |
| Options vested                               | 1,753,200  | \$ 3.768                                 | 0.906  | \$ 357                                   |

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6: - STOCKHOLDERS' EQUITY (CONT.)

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

2. Options and warrants to non-employees:

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

|   | September 30, 2016 (Unaudited) |          |             |           |
|---|--------------------------------|----------|-------------|-----------|
|   |                                | Weighted | Weighted    | Aggregate |
|   |                                | Average  | Remaining   | Intrinsic |
|   |                                | Exercise | Contractual | Value     |
|   | Number                         | Price    | Terms (in   | Price     |
|   |                                |          | years)      |           |
| Options and warrants exercisable at the end of the period | 234,013                        | \$ 5.47  | 1.97        | \$ 147    |
| Options and warrants vested and expected to vest          | 237,300                        | \$ 5.40  | 2.07        | \$ 149    |

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

The following table summarizes the activity related to unvested restricted stock and restricted stock units granted to employees and directors for the three month period ended September 30, 2016 (Unaudited):

|   | Number     |
|---|------------|
| Unvested at the beginning of period       | 1,906,619  |
| Granted                                   | 10,000     |
| Forfeited                                 | (46,485 )  |
| Vested                                    | (481,287 ) |
| Unvested at the end of the period         | 1,388,847  |
| Expected to vest after September 30, 2016 | 1,338,883  |

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.):

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

|                                     | Three<br>months<br>ended<br>September<br>30,<br>2016 2015<br>(Unaudited) |       |
|-------------------------------------|--|-------|
| Research and development expenses   | \$110  | \$320 |
| General and administrative expenses | 262  | 574   |
|                                     | \$372  | \$894 |

Unamortized compensation expenses related to restricted stock units granted to employees and directors to be recognized over an average time of approximately 2 years is approximately \$611.

4. Restricted stock and restricted stock units to consultants:

The following table summarizes the activity related to unvested restricted stock and restricted stock units granted to consultants for the three months ended September 30, 2016 (Unaudited):

|                                     | Number   |
|-------------------------------------|----------|
| Unvested at the beginning of period | 26,000   |
| Granted                             | 26,915   |
| Vested                              | (23,915) |
| Unvested at the end of the period   | 29,000   |

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

|                                     | Three<br>months<br>ended<br>September<br>30,<br>2016 2015<br>(Unaudited) |      |
|-------------------------------------|--|------|
| Research and development expenses   | \$4  | \$10 |
| General and administrative expenses | 109  | 3    |
|                                     | \$113  | \$13 |



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 clinical trials to be conducted according to our license agreement with CHA Biotech Co. Ltd.;
- our plan to execute our strategy independently, using our own personnel, and through relationships with research and clinical institutions or in collaboration with other companies;
- the prospects of entering into additional license agreements, or other forms of cooperation with other companies and medical institutions;
- our pre-clinical and clinical trials plans, including timing of initiation, enrollment and conclusion of trials;
- achieving regulatory approvals, including under accelerated paths;
- receipt of future funding from the Israel Innovation Authority, or IIA;
- our marketing plans, including timing of marketing our first product, PLX-PAD;
- developing capabilities for new clinical indications of placenta expanded (PLX) cells and new products;
- our estimations regarding the size of the global market for our product candidates;
- our expectations regarding our production capacity;
- our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;
- our expectations regarding our short- and long-term capital requirements;
- the proposed private placement of our common stock and warrants pursuant to the term sheet with Innovative Medical Management Co., Ltd., or Innovative Medical, described in the overview below, the terms of such offering, the plan to enter into definitive agreements, as well the expected approval of Innovative Medical shareholders of such term sheet;

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.

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Our business and operations are subject to substantial risks, which increase the uncertainty inherent in the forward-looking statements contained in this report. In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this periodic report would be interpreted differently in light of additional research, clinical and preclinical trials results. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading “Risk Factors” in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended June 30, 2016, or the 2016 Annual Report. Readers are also urged to carefully review and consider the various disclosures we have made in that report.

As used in this quarterly report, the terms “we”, “us”, “our”, the “Company” and “Pluristem” mean Pluristem Therapeutics Inc and our wholly owned subsidiary, Pluristem Ltd., unless otherwise indicated or as otherwise required by the context.

## Overview

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. Our lead indications are critical limb ischemia, or CLI, recovery after surgery for femoral neck fracture, and acute radiation syndrome, or ARS. Pivotal, multinational clinical trials are planned for our PLX-PAD product in CLI and femoral neck fracture, and the National Institutes of Health’s, or NIH, National Institute of Allergy and Infectious Diseases, or NIAID, is currently conducting a dose selection trial with PLX-R18 in the hematologic component of ARS. Each of these indications is a severe unmet medical need. Together, these treatments could address a multibillion dollar global market.

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

We were incorporated in Nevada in 2001, and 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 goal is to make significant progress with our robust clinical pipeline and our anticipated pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We intend to shorten the time to commercialization of our first product, PLX-PAD, by leveraging the unique accelerated regulatory pathways that exist in Europe and Japan to bring innovative products to the market efficiently, in order to address life-threatening diseases. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole. We are pursuing these accelerated pathways for PLX-PAD in CLI and femoral neck fracture. Our second product, PLX R18, is under development in the United States for ARS via the animal rule regulatory pathway, which requires no human efficacy trials for approval. We expect to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity.

In November 2016, we announced that the United Kingdom’s Medicines & Healthcare Products Regulatory Agency has cleared our application to begin the pivotal Phase III trial of PLX-PAD cells in the treatment of CLI for patients who are unsuitable for revascularization. This multinational Phase III trial will be conducted in the United States as well as Europe. We anticipate commencing patient enrollment in the first half of 2017. Our intention is to file a request for marketing authorization in the United States and in Europe following a successful completion of this

250-patient trial.

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

In February 2016, we announced that the NIAID, a part of the NIH, will initiate studies in large animals to select the appropriate doses for PLX-R18 as a medical counter measure in the treatment of the hematologic component of ARS. These studies have been initiated. Once the optimal dose is determined in large animals, a pivotal trial could be conducted, the results of which may be used to support a Biologics License Application for PLX-R18 for this indication under the Animal Rule regulatory pathway. The NIAID supports and collaborates on the dosing studies, and Pluristem supplies the PLX-R18 cells. In December 2015, we also signed a Memorandum of Understanding for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop our PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients.

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We made progress in our Phase II intermittent claudication (IC) trial, a randomized, double blind, placebo controlled, multinational clinical study. We have enrolled 166 patients to date and have expanded the clinical trial to include a total of 170 patients, with enrollment completion expected by the end of 2016. We currently have active clinical sites in the United States, Israel, Germany, and South Korea.

The FDA cleared our Investigational New Drug application to begin a Phase I trial of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT. We plan to initiate the clinical trial in the United States by the end of 2016.

In December 2015, the FDA granted our PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia. We are currently conducting additional pre-clinical studies in order to advance towards a Phase I trial.

In May 2015, we announced that the PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the EMA. In addition, we reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of CLI. The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine.

On October 25, 2016, we signed a term sheet for an investment of approximately \$30,000,000 by China-based Innovative Medical, a publicly listed Chinese company (the "Term Sheet"). The Term Sheet has been approved by Innovative Medical's Board of Directors and is subject to its shareholders' approval, which is expected to occur on or about November 9, 2016. Upon the approval of Innovative Medical's shareholders, the Term Sheet will become binding. In accordance with the Term Sheet, Innovative Medical will have the right to designate an additional director upon the closing of the agreement and, as long as it holds at least 12.5% of our issued and outstanding stock, to designate one nominee for election at our annual meeting of shareholders thereafter. Innovative Medical will also have certain information, registration and pre-emptive rights as well as certain negotiation rights with respect to our potential transactions in China.

The parties plan to enter into definitive agreements no later than December 26, 2016. Until the earlier of December 26, 2016 or the entry into the definitive agreements, we have agreed not to enter into any agreement or arrangement regarding our equity financing at a common stock price per share equal to or less than \$2.20, without the prior written consent of Innovative Medical. For further information please see "Liquidity and Capital Resources" below.

#### RESULTS OF OPERATIONS –THREE MONTHS ENDED SEPTEMBER 30, 2016 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2015.

##### Revenues

Revenues for the three month period ended September 30, 2015 were \$95,000, versus no revenues generated in the three month period ended September 30, 2016. All revenues in the period ended September 30, 2015 were derived from the United Agreement.

On December 8, 2015, we received a notice from United Therapeutics Corporation, or United, terminating our exclusive license agreement, effective immediately. As we have no further obligations towards United, we recognized the remaining upfront payment received in August 2011 as revenues during the year ended June 30, 2016.

### Research and Development Expenses, Net

Research and development expense, net (costs less participation and grants by the IIA and other parties) for the three months ended September 30, 2016 increased by 21% from \$4,128,000 for the three months ended September 30, 2015 to \$4,998,000. This increase is attributed to an increase in materials consumption and payments to consultants and subcontractors related to clinical studies such as the CLI and the HCT study. The increase was offset by decrease in stock-based compensation expenses due to the decrease in the market value of our common stock from the value on the date of the grant.

### General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2016 increased by 5% from \$1,487,000 for the three months ended September 30, 2015 to \$1,564,000, mainly due to an increase in corporate activities expenses, offset by a decrease in stock-based compensation expenses related to our directors and officers and attributable to the timing of the grants under the option plan and the market value of our common stock from the value on the date of the grant.

### Financial Income, Net

Financial income, net, increased from a net expense of \$353,000 for the three months ended September 30, 2015 to a net income of \$238,000 for the three months ended September 30, 2016. This increase is mainly attributable to increased income from exchange rates, since thorough the three months ended September 30, 2016, there was a decrease of 2% of the U.S. dollar against the New Israeli Shekel, or NIS, compared to an increase of 4% of the U.S. dollar against the NIS through the three months ended September 30, 2015, and from our hedging instruments related to the strength of the U.S. dollar against the NIS. This increase was offset by lower income related to our marketable securities (such as net gains related to sales of the marketable securities, interest and dividend income).

### Net Loss

Net loss for the three month period ended September 30, 2016 was \$6,324,000 compared to net loss of \$5,876,000 for the three month period ended September 30, 2015. The change was mainly due to the increase in research and development expenses offset by financial income, as described above. Net loss per share for the three month period ended September 30, 2016 was \$0.08, compared to \$0.07 for the three month period ended September 30, 2015.

For the three month periods ended September 30, 2016 and September 30, 2015, we had weighted average shares of common stock outstanding of 80,674,961 and 78,704,746, 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 issuances of shares related to employees and consultants, and shares issued as a result of exercises of warrants and options.

### Liquidity and Capital Resources

As of September 30, 2016, our total current assets were \$30,314,000 and total current liabilities were \$5,374,000. On September 30, 2016, we had a working capital surplus of \$24,940,000, stockholders' equity of \$32,903,000 and an accumulated deficit of \$168,081,000. We finance our operations and plan to continue doing so from our existing cash, issuances of our securities, sales of the marketable securities we hold, licensing fees and other potential payments under licensing agreements, and funds from grants from the IIA and Israel's Ministry of Economy and other research grants.

Cash and cash equivalents as of September 30, 2016 amounted to \$6,098,000 compared to \$10,805,000 as of September 30, 2015, and compared to \$6,223,000 as of June 30, 2016. Cash balances changed in the three months ended September 30, 2016 and 2015 for the reasons presented below.

Operating activities used cash of \$3,923,000 in the three months ended September 30, 2016, compared to \$3,768,000 in the three months ended September 30, 2015. Cash used in operating activities in the three months ended September 30, 2016 and 2015 consisted primarily of payments of salaries to our employees, and payments of fees to our consultants, suppliers, subcontractors, and professional services providers, including the costs of clinical studies, offset by grants by the IIA and Israel's Ministry of Economy.

Investing activities provided cash of \$3,794,000 in the three months ended September 30, 2016, compared to cash used of \$8,859,000 for the three months ended September 30, 2015. The investing activities in the three months ended September 30, 2016 consisted primarily of the withdrawal of \$1,834,000 of short term deposits and \$2,787,000 provided from the sale and redemption of marketable securities, offset by investment of \$686,000 in marketable securities and payments of \$145,000 related to investment in property and equipment. The investing activities in the three months ended September 30, 2015 consisted primarily of the investment of \$7,928,000 in short term deposits, investment of \$1,106,000 in property and equipment and investment of \$576,000 in marketable securities. Our investment activities in the three months ended September 30, 2015 also provided cash of \$746,000 from the sale and redemption of marketable securities.

Financing activities generated cash of \$4,000 during the three months ended September 30, 2016, compared to \$806,000 for the three months ended September 30, 2015. The cash generated in the three months ended September 30, 2016 from financing activities is related to exercises of options by employees. The cash generated in the three months ended September 30, 2015 from financing activities is related to proceeds received from shares issued in a private placement in May 2015, and exercises of options by employees.

During the three months ended September 30, 2016, we received cash of approximately \$2,818,000 from the IIA towards our research and development expenses. According to the IIA grant terms, we are required to pay royalties at a rate of 3% - 4% on sales of products and services derived from technology developed using this and other IIA grants until 100% of the dollar-linked grants amount plus interest are repaid. In the absence of such sales, no payment is required. Through September 30, 2016, total grants obtained aggregated to approximately \$24,018,000 and total royalties paid and accrued amounted to \$166,000.

Pursuant to the Term Sheet, Medical Management will invest in our company approximately \$30,000,000, whereby approximately 16,890,000 shares of our common stock, or the Shares, will be sold at \$1.77 per share. In addition, we will issue to Innovative Medical approximately 4,422,500 warrants to purchase shares of our common stock with an exercise price of \$2.50 per share, exercisable for a period of five years. The Shares will be subject to a lock up agreement for 6 months after the closing of the agreement.

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 2016 Annual Report.

We have an effective Form S-3 registration statement, filed under the Securities Act of 1933, as amended, with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf registration process, we may, from time to time, sell common stock, preferred stock and warrants to purchase common stock, and units of two or more of such securities in one or more offerings up to a total dollar amount of \$200,000,000. As of September 9, 2016, we have sold 6,800,000 shares of our common stock and warrants to purchase up to 4,080,000 shares of common stock in a total amount of \$17,000,000 in an offering we closed in June 2015.

## Outlook

We have accumulated a deficit of \$168,081,000 since our inception in May 2001. We do not expect to generate any revenues from sales of products in the next twelve months. Our cash needs will increase in the foreseeable future. We expect to generate revenues, which in the short and medium terms will unlikely exceed our costs of operations, from the sale of licenses to use our technology or products. Our management believes that we may need to raise additional funds before we have cash flow from operations that can materially decrease our dependence on our existing cash and other liquidity resources. We are continually looking for sources of funding, including non-diluting sources such as the IIA grants and other research grants, sales of our common stock, such as the sale pursuant to the Term Sheet, 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.

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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 2017 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, 2016 formatted in XBRL (eXtensible Business Reporting Language): (i) the Interim Condensed Consolidated Balance Sheets, (ii) the Interim Condensed Consolidated Statements of Operations, (iii) the Interim Condensed Consolidated Statements of Comprehensive Loss, (iv) the Interim Condensed Statements of Changes in Equity, (v) the Interim Condensed Consolidated Statements of Cash Flows, and (vi) the Notes to Interim Condensed Consolidated Financial Statements, tagged as blocks of text and in detail.

\*Filed herewith.

\*\* Furnished herewith.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLURISTEM THERAPEUTICS INC.

By: /s/ Zami Aberman  
Zami Aberman, Chief Executive Officer  
(Principal Executive Officer)  
Date: November 7, 2016

By: /s/ Yaky Yanay  
Yaky Yanay, Chief Financial Officer, Chief Operating Officer and President  
(Principal Financial Officer and Principal Accounting Officer)  
Date: November 7, 2016