

PLURISTEM THERAPEUTICS INC

Form 10-Q

February 06, 2019

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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 December 31, 2018

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 3508409

(Address of principal executive offices)

011-972-74-7108600

(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 every Interactive Data File required to be submitted 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 files).

Yes      No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer      Accelerated filer  
Non-accelerated filer      Smaller reporting company  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes      No

State the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date:  
116,856,573 shares of common stock issued and outstanding as of January 31, 2019.

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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 December 31, 2018

(Unaudited)

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

As of December 31, 2018

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)

	December 31, 2018	June 30, 2018
	Note	Unaudited

## ASSETS

## CURRENT ASSETS:

Cash and cash equivalents	\$ 6,796	\$8,821
Short-term bank deposits	7,917	21,079
Restricted cash and short-term bank deposits	916	687
Accounts receivable from the Israeli Innovation Authority (“IIA”)	82	58
Other current assets	2,643	1,391
<u>Total</u> current assets	18,354	32,036

## LONG-TERM ASSETS:

Long-term deposits and restricted bank deposits	379	383
Severance pay fund	837	846
Property and equipment, net	4,723	5,678
Other long-term assets	10	17
<u>Total</u> long-term assets	5,949	6,924
<u>Total</u> assets	\$ 24,303	\$38,960

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)

	December 31, 2018	June 30, 2018
	Note	Unaudited
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Trade payables	\$2,073	\$3,261
Accrued expenses	2,936	2,266
Other accounts payable	2,225	3,021
<u>Total</u> current liabilities	7,234	8,548
<b>LONG-TERM LIABILITIES</b>		
Accrued severance pay	1,110	1,127
Other long-term liabilities	765	778
<u>Total</u> long-term liabilities	1,875	1,905
<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: 116,809,444 shares as of December 31, 2018, 113,565,780		
shares as of June 30, 2018	1	1
Additional paid-in capital	248,359	244,203
Accumulated deficit	(233,166)	(215,697)
<u>Total</u> stockholders' equity	15,194	28,507
<u>Total</u> liabilities and stockholders' equity	\$24,303	\$38,960

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

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Note	Six months ended December 31		Three months ended December 31,	
		2018	2017	2018	2017
Revenues		\$54	\$50	\$50	\$50
Cost of revenues		(2)	(2)	(2)	(2)
Gross profit		52	48	48	48
Operating Expenses:					
Research and development expenses		(15,197)	(11,451)	(7,432)	(6,259)
Less: participation by the IIA and other parties		2,177	1,136	1,176	621
Research and development expenses, net		(13,020)	(10,315)	(6,256)	(5,638)
General and administrative expenses, net		(4,333)	(5,683)	(2,123)	(2,920)
Other income	7	-	43	-	43
Operating loss		(17,301)	(15,907)	(8,331)	(8,467)
Financial income (expense), net		(168)	293	(352)	238
Net loss for the period		\$(17,469)	\$(15,614)	\$(8,683)	\$(8,229)
Loss per share:					
Basic and diluted net loss per share		\$(0.15)	\$(0.15)	\$(0.07)	\$(0.08)
Weighted average number of shares used in computing basic and diluted net loss per share		114,723,358	101,224,325	115,790,930	105,130,191

(\*) 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 COMPREHENSIVE LOSS (UNAUDITED)

U.S. Dollars in thousands

	Six months ended		Three months ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Net loss	\$(17,469)	\$(15,614)	\$(8,683)	\$(8,229)
Other comprehensive income, net:				
Unrealized gain on available-for-sale marketable securities, net	-	4,307	-	5,440
Reclassification adjustment of available-for-sale marketable securities losses realized in net loss, net	-	(928 )	-	(1,006)
Other comprehensive income	-	3,379	-	4,434
Total comprehensive loss	\$(17,469)	\$(12,235)	\$(8,683)	\$(3,795)

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 STOCKHOLDERS' EQUITY

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

	Common Stock Shares	Amount	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Other Comprehensive Income Deficit	Accumulated Stockholders' Equity	Total Stockholders' Equity
Balance as of July 1, 2017	96,938,789	\$ 1	\$ 217,822	\$ 1,999	\$ (189,571 )	\$ 30,251	
Exercise of options by employees	5,000	-	5	-	-	5	
Stock-based compensation to employees, directors and non-employee consultants	1,731,024	(* )	3,108	-	-	3,108	
Issuance of common stock under At-The Market ("ATM") Agreement, net of issuance costs of \$80 (Note 6a)	834,040	(* )	1,026	-	-	1,026	
Issuance of common stock, net of issuance costs of \$1,405 (Note 6b)	9,000,000	(* )	13,646	-	-	13,646	
Exercise of warrants by investors (Note 6c)	828,703	(* )	1,160	-	-	1,160	
Other comprehensive income, net	-	-	-	3,379	-	3,379	
Net loss	-	-	-	-	(15,614 )	(15,614 )	
Balance as of December 31, 2017 (unaudited)	109,337,556	\$ 1	\$ 236,767	\$ 5,378	\$ (205,185 )	\$ 36,961	

(\*) 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 STOCKHOLDERS' EQUITY

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

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of July 1, 2018	113,565,780	\$ 1	\$244,203	\$ (215,697 )	\$ 28,507
Stock-based compensation to employees, directors and non-employee consultants	1,519,164	(* )	2,196	-	2,196
Issuance of common stock under ATM Agreement, net of issuance costs of \$148 (Note 6a)	1,706,000	(* )	1,952	-	1,952
Exercise of options by employees and non-employee consultants	18,500	(* )	8	-	8
Net loss	-	-	-	(17,469 )	(17,469 )
Balance as of December 31, 2018 (unaudited)	116,809,444	\$ 1	\$248,359	\$ (233,166 )	\$ 15,194

(\*) 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

	Six months ended December 31,	
	2018	2017
		as adjusted, see note 2
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(17,469)	\$(15,614)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,001	1,023
Accretion of discount, amortization of premium and changes in accrued interest of marketable securities	-	12
Gain from sale of investments of available-for-sale marketable securities	-	(928 )
Other-than-temporary loss of available-for-sale marketable securities (see Note 3)	-	850
Stock-based compensation to employees, directors and non-employee consultants	2,196	3,108
Decrease (increase) in accounts receivable from the IIA	(24 )	864
Decrease (increase) in other current assets and other long-term assets	(1,245 )	272
Decrease in trade payables	(1,041 )	(86 )
Increase (decrease) in other accounts payable, accrued expenses, other current liabilities and other long-term liabilities	(246 )	421
Decrease (increase) in interest receivable on short-term deposits	60	(28 )
Linkage differences and interest on short and long-term deposits and restricted bank deposits	3	2
Accrued severance pay, net	(8 )	86
Net cash used by operating activities	\$(16,773)	\$(10,018)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$(193 )	\$(185 )
Proceeds from (investment in) short-term deposits	13,109	(9,714 )
Investment in long-term deposits and restricted bank deposits	(6 )	-
Proceeds from sale of available-for-sale marketable securities	-	9,010
Proceeds from redemption of available-for-sale marketable securities	-	9
Investment in available-for-sale marketable securities	-	(1,146 )
Net cash provided by investing activities	\$12,910	\$(2,026 )

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

	Six months ended December 31,	
	2018	2017
		as adjusted, see note 2
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds related to issuance of common stock, net of issuance costs	\$ 1,952	\$ 14,672
Exercise of warrants and options	8	1,165
Proceeds with respect to Israel-United States Binational Industrial Research and Development Foundation liability	107	88
Net cash provided by financing activities	\$ 2,067	\$ 15,925
Increase (decrease) in cash and cash equivalents and restricted cash	(1,796)	3,881
Cash and cash equivalents and restricted cash at the beginning of the period	9,508	5,266
Cash and cash equivalents and restricted cash at the end of the period	\$ 7,712	\$ 9,147
(a) Supplemental disclosure of cash flow activities:		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$ 5	\$ 6
(b) Supplemental disclosure of non-cash activities:		
Purchase of property and equipment on credit	\$ 24	\$ 16

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. a. has a wholly owned subsidiary, Pluristem Ltd. (the “Subsidiary”), which is incorporated under the laws of the State of Israel. Pluristem Therapeutics Inc. and the Subsidiary are referred to as the “Company” or “Pluristem”.

The Company’s shares of common stock are traded on the Nasdaq Capital Market under the symbol “PSTI” and on the Tel-Aviv Stock Exchange under the symbol “PLTR”.

b. The Company is a bio-therapeutics company developing placenta-based cell therapy product candidates for the treatment of multiple ischemic and inflammatory conditions. The Company has incurred an accumulated deficit of approximately \$233,166 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of December 31, 2018, the Company’s total stockholders' equity amounted to \$15,194.

During the six month period ended December 31, 2018, the Company incurred operating losses of \$17,301 and its negative cash flow from operating activities was \$16,773. The Company will be required to identify additional liquidity resources in the near term in order to support the commercialization of its products and maintain its research and development and clinical trials activities.

As of December 31, 2018, the Company's cash position (cash and cash equivalents and short-term bank deposits) totaled approximately \$14,713. The Company is addressing its liquidity issues by implementing initiatives to allow the continuation of its activities. The Company's current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures. The Company's ability to successfully carry out its business plan, which includes a cost-reduction plan should it be unable to raise sufficient additional capital, is primarily dependent upon its ability to (1) obtain sufficient additional capital, (2) enter into license agreements to use or commercialize the Company’s products and (3) receive other sources of funding, including non-diluting sources such as the IIA grants, the European Union's Horizon 2020 program (“Horizon 2020”) grants and other grants. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its products.

According to management estimates, liquidity resources as of December 31, 2018, will be sufficient to maintain the Company's operations into the beginning of the first quarter of the Company's fiscal year 2020. The Company's inability to raise funds to carry out its business plan will have a severe negative impact on its ability to remain a viable company.

CHA Agreement

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

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.

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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.)

Upon the first regulatory approval for a PLX product in South Korea, for the specified Indications, Pluristem and CHA will establish an equally owned joint venture to commercialize PLX cell products in South Korea. Pluristem will be able to use the data generated by CHA to pursue the development of PLX product candidates outside of South Korea.

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

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

In March 2015, the Company sold a portion of the CHA shares received in December 2013. In January 2018, the Company sold its remaining investment in the CHA shares, for aggregate net proceeds of approximately \$10,500, representing a net gain of \$6,200, which is recorded in "Financial income, net" for the fiscal year ended June 30, 2018, and reclassified from other comprehensive loss.

Chart Industries Agreement

In November 2018, the Company entered into a license agreement with a subsidiary of Chart Industries, Inc. ("Chart") regarding the Company's thawing device for cell-based therapies. Pursuant to the terms of the agreement, Chart obtained the exclusive rights to manufacture and market the thawing device in all territories worldwide, excluding Greater China, and the Company is to receive royalties from sales of the product and supply of an agreed upon number of thawing devices. Royalties shall commence on the date of Chart's first commercial sale of the thawing device.

NOTE 2:-SIGNIFICANT ACCOUNTING POLICIES

a. Unaudited Interim Financial Information

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

For further information, reference is made to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2018.

Operating results for the three and six month periods ended December 31, 2018, are not necessarily indicative of the results that may be expected for the year ending June 30, 2019.

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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:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

b. Significant Accounting Policies

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

c. Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates, judgments and assumptions that are reasonable based upon information available at the time they are made.

These estimates, judgments and assumptions can affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. Fair value of financial instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, short-term and restricted bank deposits, accounts receivable and other current assets, trade payable and other accounts payable, accrued expenses and other liabilities, approximate fair value because of their generally short term maturities.

The Company measures its investments in marketable securities and derivative instruments at fair value under Accounting Standards Codification (“ASC”), “Fair Value Measurements and Disclosures” (“ASC 820”). Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 - Unobservable inputs for the asset or liability.

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

e. Derivative financial instruments

The Company accounts for derivatives and hedging based on ASC 815, “Derivatives and hedging” (“ASC 815”), as amended and related interpretations. ASC 815 requires the Company to recognize all derivatives on the balance sheet at fair value.



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:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

If a derivative meets the definition of a hedge and is so designated, depending on the nature of the hedge, changes in the fair value of the derivative will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings (for fair value hedge transactions) or recognized in other comprehensive income (loss) until the hedged item is recognized in earnings (for cash flow hedge transactions).

The ineffective portion of a derivative's change in fair value is recognized in earnings. If a derivative does not meet the definition of a hedge, the changes in the fair value are included in earnings. Cash flows related to such hedges are classified as operating activities.

The Company enters into forward exchange contracts and option contracts in order to limit the exposure to exchange rate fluctuation associated with expenses mainly incurred in New Israeli Shekels ("NIS"). Since the derivative instruments that the Company holds do not meet the definition of hedging instruments under ASC 815, any gain or loss derived from such instruments is recognized immediately as "financial income, net".

The Company measured the fair value of the contracts in accordance with ASC 820. Foreign currency derivative contracts are classified within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments.

As of December 31, 2018, the fair value of the options contracts was approximately (\$348), presented in "other accounts payable" (see Note 4). The net income (losses) recognized in "Financial income (expenses), net" during the three and six month periods ended December 31, 2018 and 2017 were (\$228), (\$105) and (\$74), (\$217), respectively.

f. Recently Adopted Accounting Pronouncement

ASU No. 2016-15 - "Statement of Cash Flows" (Topic 230) ("ASU No. 2016-15"):

In August 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-15, which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU No. 2016-15 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2016-15 in the first quarter of fiscal year 2019 and it did not have a material impact on the Company's consolidated financial statements and related disclosures.

ASU No. 2016-18 - "Statement of Cash Flows" (Topic 230) ("ASU No. 2016-18"):

In November 2016, the FASB issued ASU 2016-18. The ASU requires that the consolidated statement of cash flows include the change in total cash and cash equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. ASU No. 2016-18 also requires a reconciliation between the total of cash and cash equivalents and restricted cash presented on the consolidated statement of cash flows and the cash and cash equivalents balance presented on the consolidated balance sheet. ASU No. 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. The standard requires application using a retrospective transition method. The Company adopted this standard effective July 1, 2018 using the retrospective transition method, as required by the new standard.

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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:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The following table provides a reconciliation of cash and cash equivalents, and long term restricted cash reported within the consolidated balance sheets that sum to the total of such amounts in the consolidated statements of cash flows:

	Six months ended	
	December 31, 2018	2017
	(Unaudited)	
Cash and cash equivalents	\$6,796	\$8,581
Restricted cash included in Restricted cash and short-term bank deposits	916	566
Cash, cash equivalents and restricted cash shown in the consolidated statement of cash flows	\$7,712	\$9,147

## Recently Issued Accounting Pronouncements

ASU No. 2016-02 - "Leases" ("Topic 842"):

In February 2016, the FASB issued guidance on the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether a lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a manner similar to the accounting treatment requirements under existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. Topic 842 supersedes the previous leases standard, ASC 840, "Leases". The guidance is effective for annual periods beginning on or after December 15, 2018, or July 1, 2019 for the Company, and interim periods within those fiscal years with early adoption permitted. Early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach.

In July 2018, the FASB issued ASU No. 2018-11, "Targeted Improvements - Leases (Topic 842)", which further updated Topic 842. This update provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented.

If elected, an entity would recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company is currently evaluating the potential impact of the guidance on its consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

ASU No. 2017-12 - “Derivatives and Hedging - Targeted Improvements to Accounting for Hedging Activities” (“ASU No. 2017-12”):

In August 2017, the FASB issued ASU No. 2017-12, which is intended to simplify and amend the application of hedge accounting to more clearly portray the economics of an entity’s risk management strategies in its financial statements. The ASU will make more financial and nonfinancial hedging strategies eligible for hedge accounting, reduce complexity in fair value hedges of interest rate risk and ease certain documentation and assessment requirements of hedge effectiveness. It also changes how companies assess effectiveness of the hedge and amends the presentation and disclosure requirements relating to hedging activities. ASU 2017-12 is effective for fiscal years beginning after December 15, 2018, or July 1, 2019, for the Company. The Company is currently evaluating the potential impact of adopting the ASU on its consolidated financial statements.

ASU No. 2018-07 - “Compensation—Stock Compensation” (Topic 718) (“ASU No. 2018-07”):

In June 2018, the FASB issued ASU No. 2018-07. The ASU expands the scope of ASU No. 2018-07 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply ASU No. 2018-07 to nonemployee awards except with respect to option pricing models and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that ASU No. 2018-07 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018, or July 1, 2019 for the Company, and interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the potential impact of the guidance on its consolidated financial statements.

ASU No. 2018-18 - “Collaborative Arrangements (Topic 808) —Clarifying the Interaction between Topic 808 and Topic 606” (“ASU No. 2018-18”):

In November 2018, the FASB issued ASU No. 2018-18, which clarifies the interaction between Topic 808 and Topic 606 by (1) clarifying that certain transactions between collaborative arrangement participants should be accounted for under Topic 606, (2) adding unit-of-account guidance in Topic 808 to align with the guidance in Topic 606, and (3) clarifying presentation guidance for transactions with a collaborative arrangement participant that are not accounted for under Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, or July 1, 2019 for the Company. The Company is currently evaluating the impact of adopting the ASU on its consolidated financial statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 3:- MARKETABLE SECURITIES

During the year ended June 30, 2018, the Company sold marketable securities for aggregate net proceeds (including redemptions of certain bonds) of approximately \$21,890, representing a net gain of \$8,440. The proceeds from the sale of such marketable securities are included in "Financial income, net", for the year ended June 30, 2018.

In addition, during the year ended June 30, 2018, the Company recognized an-other-than-temporary impairment loss on an outstanding security of \$850, and the value of the outstanding security was amortized in full.

NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

	December		June 30,	
	31, 2018		2018	
	(Unaudited)			
	Level	Level	Level	Level
	1	2	1	2
Foreign currency derivative instruments	-	(348 )	-	(243)
Total financial liabilities	\$-	\$ (348 )	\$-	\$ (243)

NOTE 5: - COMMITMENTS AND CONTINGENCIES

a. As of December 31, 2018, an amount of \$1,285 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% 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 December 31, 2018, total grants obtained from the IIA aggregated to approximately \$27,096 and total royalties paid and accrued amounted to \$170. As of December 31, 2018, the Company's contingent liability in respect to royalties to the IIA amounted to \$26,926, not including LIBOR interest as described above.

c. The Company was awarded a marketing grant under the "Smart Money" program of the Israeli Ministry of Economy and Industry. The program's aim is to assist companies to extend their activities in international markets. The goal market that was chosen was Japan. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in Japan and for regulatory

activities there.

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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 5: - COMMITMENTS AND CONTINGENCIES (CONT.)

As part of the program, the Company will repay royalties of 5% from the Company's income in Japan during five years, starting the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread for a period of up to 5 years or until the amount of the grant is fully paid.

As of December 31, 2018, total grants obtained under this Smart Money program amounted to approximately \$112. As of December 31, 2018, the Company's contingent liability with respect to royalties for this "Smart Money" program was \$112 and no royalties were paid or accrued.

The Company was awarded an additional "Smart Money" grant of approximately \$229 from Israel's Ministry of Economy and Industry to facilitate certain marketing and business development activities with respect to its advanced cell therapy products in the Chinese market, including Hong Kong. The Israeli government granted the Company budget resources that are intended to be used to advance the Company's product candidate towards marketing in the China-Hong Kong markets.

The Company will also receive close support from Israel's trade representatives stationed in China, including Hong Kong, along with experts appointed by the Smart Money program. As part of the program, the Company will repay royalties of 5% from the Company's revenues in the region for a five year period, beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and will be spread for a period of up to 5 years or until the amount of the grant is fully paid.

As of December 31, 2018, the aggregate amount of grant obtained from this Smart Money program was approximately \$24. As of December 31, 2018, the Company's contingent liability with respect to royalties for this "Smart Money" program is \$24 and no royalties were paid or accrued.

In September 2017, the Company signed an agreement with the Tel-Aviv Sourasky Medical Center (Ichilov e. Hospital) to conduct a Phase I/II trial of PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease ("GvHD").

As part of the agreement with the Tel-Aviv Sourasky Medical Center (Ichilov Hospital), the Company will pay royalties of 1% from its net sales of the PLX-PAD product relating to GvHD, with a maximum aggregate royalty amount of approximately \$250.

f. The Company currently collaborates with the New York Blood Center ("NYBC") on preclinical studies of its placental expanded R-18 cells ("PLX-R18") to enhance the efficacy of umbilical cord blood transplantation. The project was selected to receive a conditional award of \$900 from the Israel-United States Binational Industrial Research and Development Foundation (the "BIRD Foundation"), of which an amount of \$585 is a direct grant allocated to the Company. Per the terms of the project, the Company will provide the PLX-R18 cells and the NYBC will be responsible for conducting and supporting the studies. Amounts received in connection with this award are presented in "Other long-term liabilities", as the Company does not expect to repay the liability in the next 12 months. In accordance with the agreement between the Company and NYBC, if only one party elects to proceed with the development of the product, such party shall be responsible for all repayment obligations to the BIRD Foundation for both parties, if applicable. In addition, in case of conclusion of project development which will trigger the grant repayment to the BIRD Foundation, if the Company will elect to pursue the development of the product, and NYBC elects not to pursue the development of the product, then, unless otherwise agreed by the parties, the Company shall

pay NYBC royalties in the amount of 2.5% from its revenues of the product, up to an aggregate royalty amount of approximately \$550.

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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 5: - COMMITMENTS AND CONTINGENCIES (CONT.)

The Company was awarded a marketing grant of approximately \$52 under the "Shalav" program of the Israeli Ministry of Economy and Industry. The grant is intended to facilitate certain marketing and business development activities with respect to the Company's advanced cell therapy products in the U.S. market. As part of the program, the Company will repay royalties of 3%, but only with respect to the Company's revenues in the U.S. market in excess of \$250 of its revenues in fiscal year 2018, upon the earlier of the five year period beginning the year in which the Company will not be entitled to reimbursement of expenses under the program and/or until the amount of the grant, which is linked to the Consumer Price Index, is fully paid. As of December 31, 2018, no funds have been received.

NOTE 6: - STOCKHOLDERS' EQUITY

Pursuant to a shelf registration on Form S-3 declared effective by the Securities and Exchange Commission on June 23, 2017, in July 2017 the Company entered into an At Market Issuance Sales Agreement ("ATM Agreement") with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc. (collectively, the "Agents"), which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of common stock having an aggregate offering price of up to \$80,000 through the Agents acting as sales agent. During the six month period ended December 31, 2018, the Company sold 1,706,000 shares of common stock under the ATM Agreement at an average price of \$1.23 per share for aggregate net proceeds of approximately \$1,952, net of issuance expenses of \$148.

On February 4, 2019, the Company notified the Agents of the termination of the ATM Agreement.

On October 31, 2017, the Company completed a public offering in Israel, pursuant to the Company's existing shelf registration statement on Form S-3 in the United States and a shelf registration statement filed in Israel, pursuant to which the Company raised aggregate gross proceeds of \$15,051 through the sale of 9,000,000 shares of the Company's common stock at a purchase price of NIS 5.90 (approximately \$1.67) per share. The net proceeds, after deducting fees and expenses related to the offering, were approximately \$13,646.

Through the six month period ended December 31, 2017, a total of 828,703 warrants were exercised by investors at an exercise price of \$1.40 per share, resulting in the issuance of 828,703 shares of common stock for net proceeds of approximately \$1,160.

## 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.)

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

## 1. Options to employees and directors:

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

	Six months ended December 31, 2018 (Unaudited)			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	315,000	\$ 0.62	-	-
Options forfeited	(307,500)	\$ 0.62	-	-
Options exercised	(7,500 )	\$ 0.62	-	-
Options outstanding at end of the period	-	-	-	-

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 employee and director option holders had all option holders exercised their options on December 31, 2018. This amount changes based on the fair market value of the Company's common stock.

## 2. Options to non-employees:

The Company accounts for its options to non-employees under the fair value method in accordance with ASC 718. A summary of the options to non-employee consultants under its 2005 and 2016 incentive option plans is as follows:

	Six months ended December 31, 2018 (Unaudited)			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	500,600	\$ 0.01	-	-
Options granted	498,050	-	-	-
Options exercised	(11,000 )	0.28	-	-
Options forfeited	(1,850 )	-	-	-
Options outstanding at end of the period	985,800	\$ -	8.26	\$ 779

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Options exercisable at the end of the period	264,586	\$ -	6.56	\$ 209
Options vested and expected to vest	985,800	\$ -	8.26	\$ 779

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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.)

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

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

	Six months ended December 31, 2018		Three months ended December 31, 2017	
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 97	\$ 6	\$ 13	\$ 3
General and administrative expenses	\$ 27	\$ 28	\$ 21	\$ 13
	\$ 124	\$ 34	\$ 34	\$ 16

3. RS and RSUs to employees and directors:

The following table summarizes the activity related to unvested RS and RSUs granted to employees and directors under the Company's 2005 and 2016 incentive option plans for the six month period ended December 31, 2018 (Unaudited):

	Number
Unvested at the beginning of period	6,293,608
Granted	4,876,000
Forfeited	(339,194 )
Vested	(1,369,817)
Unvested at the end of the period	9,460,597
Expected to vest after December 31, 2018	9,137,684

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.)

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

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

	Six months ended		Three months ended	
	December 31,		December 31,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Research and development expenses	\$440	\$331	\$121	\$187
General and administrative expenses	1,354	2,567	623	1,277
	\$1,794	\$2,898	\$744	\$1,464

Unamortized compensation expenses related to RSUs granted to employees and directors to be recognized over an average time of approximately 4 years are approximately \$6,899.

4. RS and RSUs to consultants:

The following table summarizes the activity related to unvested RS and RSUs granted to consultants under the Company's 2005 and 2016 incentive option plans for the six month period ended December 31, 2018 (Unaudited):

	Number
Unvested at the beginning of period	199,559
Granted	411,760
Vested	(149,347)
Unvested at the end of the period	461,972

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

	Six months ended		Three months ended	
	December 31,		December 31,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Research and development expenses	\$18	\$3	\$(8)	\$3
General and administrative expenses	260	173	98	122
	\$278	\$176	\$90	\$125

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 7:-OTHER INCOME

In December 2017, the Subsidiary was awarded approximately \$43 (NIS 150) by the Israeli Ministry of Labor, Social Affairs and Social Services related to its “Equal Employment” program which aims to reward and honor Israeli employers who demonstrate and promote gender equality in employment.

NOTE 8:-SUBSEQUENT EVENTS

On February 4, 2019, Pluristem delivered notice to the Agents of its termination of the ATM Agreement, effective as of February 6, 2019.

On February 6, 2019, Pluristem entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sales Agreement, with Jefferies LLC, as agent, pursuant to which Pluristem may issue and sell shares of its common stock having an aggregate offering price of up to \$50,000 from time to time through Jefferies LLC. Pluristem is not obligated to make any sales of common stock under the Sales Agreement.

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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;
- the expected timing of the release of data from our various studies;
- achieving regulatory approvals, including under accelerated paths;
- receipt of future funding from the Israel Innovation Authority, or IIA, the European Union's Horizon 2020 program as well as grants from other independent third parties;
- our marketing plans, including timing of marketing our product candidates, PLX-PAD and PLX-R18;
- developing capabilities for new clinical indications of placenta expanded (PLX) cells and new products;
- the timing and development of our PLX-Immune product candidate;
- our estimations regarding the size of the global market for our product candidates;
- our expectations regarding our production capacity;
- our expectation to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity;
- our expectations regarding our short- and long-term capital requirements;



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

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

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

Our business and operations are subject to substantial risks, which increase the uncertainty inherent in the forward-looking statements contained in this report.

In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this periodic report would be interpreted differently in light of additional research, clinical and preclinical trials results. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading "Risk Factors" in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended June 30, 2018, or the 2018 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 following surgery for hip fracture, and acute radiation syndrome, or ARS. Each of these indications is a severe unmet medical need. 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.

PLX cells are derived from a class of placental cells that are harvested from donated placenta at the time of full term healthy delivery of a baby. PLX cell products require no tissue matching prior to administration. They are produced using our proprietary three-dimensional expansion technology. Our manufacturing facility complies with the European, Japanese, Israeli and U.S. Food and Drug Administration, or FDA's, current Good Manufacturing Practice requirements and has been approved by the European and Israeli regulators for production of PLX-PAD for late stage trials. In December 2017, after an audit of our facilities, we were granted manufacturer/importer authorization and Good Manufacturing Practice Certification by Israel's Ministry of Health. If we obtain FDA and other regulatory approvals to market PLX cells, we expect to have in-house production capacity to grow clinical-grade PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our anticipated pivotal trials in order to ultimately bring innovative, potent therapies to patients who need new treatment options. We expect to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity. Our business model for commercialization and revenue generation includes, but is not limited to, direct sale of our products, partnerships, licensing deals, and joint ventures with pharmaceutical companies.

We aim to shorten the time to commercialization of our product candidates by leveraging unique accelerated regulatory pathways that exist in the United States, Europe and Japan to bring innovative products that address life-threatening diseases to the market efficiently. We believe that these accelerated pathways create substantial opportunities for us and for the cell therapy industry as a whole.

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Two pivotal, Phase III multinational clinical trials are currently being conducted with our PLX-PAD product candidate: one in CLI, and the other in recovery following surgery for hip fracture. Based on our current patient enrollment progress, we expect to complete the follow up of our Phase III study in CLI in the first half of 2020 with respect to Europe, and in the first half of 2021 with respect to the United States. In addition, based on our current patient enrollment progress, we expect to complete the follow up of our Phase III study in recovery following surgery for hip fracture in the second half of 2020. We expect to release the clinical data shortly after the conclusion of the follow ups.

Our PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines Agency, or EMA, Japan's Pharmaceuticals and Medical Devices Agency, or PMDA accelerated pathway, the FDA Fast Track Designation and FDA Expanded Access Program, or EAP, in the United States. The CLI program in the European Union was awarded a Euro 7,600,000 (approximately \$8,900,000) grant as part of the European Union's Horizon 2020 program and to date we have received a portion of such grant.

Our PLX-PAD cell program in recovery following surgery for hip fracture was also selected for the Adaptive Pathways pilot project of EMA and was awarded a Euro 7,400,000 (approximately \$8,600,000) grant as part of the European Union's Horizon 2020 program and to date we have received a portion of such grant.

Our second product candidate, PLX-R18, is under development in the United States for ARS via the FDA Animal Rule regulatory pathway, and, based on our assessment, is ready for a pivotal trial, which may also result in approval without the prior performance of human efficacy trials. The National Institutes of Health's National Institute of Allergy and Infectious Diseases has completed a dose selection trial with our PLX-R18 product candidate in the hematologic component of ARS. Assuming we receive a contract from the U.S. government, we expect to initiate an ARS pivotal trial in the second half of 2019.

In July 2018, we entered into a strategic collaboration agreement with Thermo Fisher Scientific Inc. with the aim of advancing the fundamental knowledge of cell therapy industrialization and to improve quality control of the end-to-end supply chain. The collaboration will combine Thermo Fisher's experience in cell therapy development and bio production scale up with our expertise in cell therapy manufacturing, clinical development and quality control.

In September 2018, we announced that the FDA granted Orphan Drug Designation to our PLX cell therapy for the treatment of graft failure and incomplete hematopoietic recovery following hematopoietic cell transplantation.

In October 2018, we announced that the FDA approved cost recovery for our PLX-PAD under an EAP held by World Trials, Inc., a privately held third party cost recovery sponsor. Under the terms of the EAP, an initial 100 Rutherford-5 CLI patients who are ineligible for inclusion under our ongoing Phase 3 study protocol, and whose condition is life-threatening, can be enrolled.

In November 2018, we entered into a license agreement with a subsidiary of Chart Industries, Inc. ("Chart") regarding our thawing device for cell-based therapies. Pursuant to the terms of the agreement, Chart obtained the exclusive rights to manufacture and market the thawing device in all territories worldwide, excluding Greater China, and we are to receive royalties from sales of the product and supply of an agreed upon number of thawing devices. Royalties shall commence on the date of Chart's first commercial sale of the thawing device.

In January 2019, we announced a successful one-year follow up of a compassionate use treatment in a Buerger's disease patient treated with our PLX-PAD cell therapy.

In January 2019, we announced the receipt of a joint grant awarded by the Israeli Ministry of Defense and the IIA for the pre-clinical development of our PLX cells for the treatment of burn injuries. This project entails collaboration between us, the Israeli Defense Forces (IDF) medical corps and professionals who specialize in burn injuries from Israeli hospitals.



RESULTS OF OPERATIONS – SIX AND THREE MONTHS ENDED DECEMBER 31, 2018 COMPARED TO SIX AND THREE MONTHS ENDED DECEMBER 31, 2017.

Revenues

Revenues for the six and three month periods ended December 31, 2018 were \$53,500 and \$50,000, respectively, as compared to \$50,000 in the six and three month periods ended December 31, 2017. All revenues in the three and six month periods ended December 31, 2018 and 2017 were related to the sale of our PLX cells for research use.

Research and Development Expenses, Net

Research and development expense, net (costs less participation and grants by the IIA and other parties) for the six month period ended December 31, 2018 increased by 26% from \$10,315,000 for the six month period ended December 31, 2017 to \$13,020,000. The increase is mainly attributed to: (1) an increase in subcontractor expenses related to some of our clinical studies, (2) an increase in materials consumption, (3) a decrease in IIA participation (\$1,500,000 was approved in calendar year 2017 compared to \$900,000 that was approved in calendar year 2018), (4) an increase in payroll expenses related to increases in average salaries, and (5) an increase in stock-based compensation expenses due to the amount of restricted stock units granted. The increase was partially offset by a higher participation by the European Union with respect to the Horizon 2020 grants which commenced in calendar year 2017.

Research and development expense, net (costs less participation and grants by the IIA and other parties) for the three months ended December 31, 2018 increased by 11% from \$5,638,000 for the three months ended December 31, 2017 to \$6,256,000. The increase is mainly attributed to: (1) an increase in subcontractor expenses related to some of our clinical studies, (2) an increase in materials consumption, and (3) a decrease in IIA participation (\$1,500,000 was approved in calendar year 2017 compared to \$900,000 that was approved in calendar year 2018). The increase was partially offset by a higher participation by the European Union with respect to the Horizon 2020 grants which commenced in calendar year 2017.

General and Administrative Expenses

General and administrative expenses for the six month period ended December 31, 2018 decreased by 24% from \$5,683,000 for the six month period ended December 31, 2017 to \$4,333,000. This decrease is attributed to a decrease in stock-based compensation expenses related to the amount of restricted stock units granted and their vesting schedules, and a decrease in corporate activities expenses.

General and administrative expenses for the three months ended December 31, 2018 decreased by 27% from \$2,920,000 for the three months ended December 31, 2017 to \$2,123,000. This decrease is attributed to a decrease in stock-based compensation expenses related to the amount of restricted stock units granted and their vesting schedules, and a decrease in corporate activities expenses.

Financial Income (Expense), Net

Financial income, net, decreased from a net financial income of \$293,000 for the six month period ended December 31, 2017 to a net financial expense of \$168,000 for the six month period ended December 31, 2018. This decrease is mainly attributable to changes in the fair value of our hedging instruments related to the strength of the U.S. dollar against the NIS and lower income due to the sale of our marketable securities which occurred in the six months ended December 31, 2017. The decrease was partially offset by an increase in interest on deposits due to our investments in short-term deposits.

Financial income, net, decreased from a net financial income of \$238,000 for the three months ended December 31, 2017 to a net financial expense of \$352,000 for the three months ended December 31, 2018. This decrease is mainly attributable to changes in the fair value of our hedging instruments related to the strength of the U.S. dollar against the NIS. The decrease was partially offset by an increase in interest on deposits due to our investments in short-term deposits.

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## Net Loss

Net loss for the six and three month periods ended December 31, 2018 was \$17,469,000 and \$8,683,000, respectively, as compared to net loss of \$15,614,000 and \$8,229,000 for the six and three month periods ended December 31, 2017, respectively. The changes were mainly due to the increase in research and development expenses, as described above. Net loss per share for the six and three month periods ended December 31, 2018 was \$0.15 and \$0.07, respectively, as compared to \$0.15 and \$0.08 for the six and three month periods ended December 31, 2017.

For the six and three month periods ended December 31, 2018 and December 31, 2017, we had weighted average shares of common stock outstanding of 114,723,358, 115,790,930 and 101,224,325, 105,130,191, respectively, which were used in the computations of net loss per share for the six and three month periods.

The increase in weighted average common shares outstanding reflects the issuance of additional shares mainly related to the issuances of shares from a public offering we conducted in October 2017, issuances of shares to employees and consultants, issuances of shares pursuant to our At Market Issuance Sales Agreement, or the ATM Agreement, and shares issued as a result of exercises of options.

## Liquidity and Capital Resources

As of December 31, 2018, our total current assets were \$18,354,000 and total current liabilities were \$7,234,000. On December 31, 2018, we had a working capital surplus of \$11,120,000, stockholders' equity of \$15,194,000 and an accumulated deficit of \$233,166,000. We finance our operations, and plan to continue doing so, from our existing cash, issuances of our securities and funds from grants from the IIA, European Union's Horizon 2020 program, Israel's Ministry of Economy, and other research grants.

Our cash and cash equivalents as of December 31, 2018 amounted to \$6,796,000 compared to \$8,581,000 as of December 31, 2017, and compared to \$8,821,000 as of June 30, 2018. Cash balances changed in the six months ended December 31, 2018 and 2017 for the reasons presented below.

Operating activities used cash of \$16,773,000 in the six months ended December 31, 2018, compared to \$10,018,000 in the six months ended December 31, 2017. Cash used in operating activities in the six months ended December 31, 2018 and 2017 consisted primarily of payments of salaries to our employees and payments of fees to our consultants, suppliers, subcontractors, and professional services providers, including the costs of clinical studies, offset by grants from the IIA, Horizon 2020, Israel's Ministry of Economy and other research grants.

Investing activities provided cash of \$12,910,000 in the six months ended December 31, 2018, compared to cash used of \$2,026,000 for the six months ended December 31, 2017. The investing activities in the six month period ended December 31, 2018 consisted primarily of the withdrawal of \$13,109,000 of short term deposits, offset by payments of \$193,000 related to investment in property and equipment. The investing activities in the six months ended December 31, 2017 consisted primarily of \$9,714,000 related to investment in short term deposits, investment of \$1,146,000 in marketable securities and payments of \$185,000 related to investment in property and equipment, offset by cash provided from the sale and redemption of marketable securities of \$9,019,000.

Financing activities generated cash of \$2,067,000 during the six months ended December 31, 2018, compared to \$15,925,000 for the six months ended December 31, 2017. The cash generated in the six months ended December 31, 2018 from financing activities is related to net proceeds of \$1,952,000 from issuing shares of our common stock under our ATM Agreement, proceeds of \$107,000 related to a grant received from the Israel-United States Binational Industrial Research and Development Foundation and net proceeds of \$8,000 from the exercise of options. The cash generated in the six months ended December 31, 2017 from financing activities is related to net proceeds of \$13,646,000 from issuing shares of our common stock in a public offering we conducted in October 2017, net

proceeds of \$1,160,000 from issuing shares of our common stock from the exercise of warrants, net proceeds of \$1,026,000 from issuing shares of our common stock under our ATM Agreement, proceeds of \$88,000 related to grant received from the Israel-United States Binational Industrial Research and Development Foundation and net proceeds of \$5,000 from exercises of options by employees.

In July 2017, we entered into the ATM Agreement with FBR Capital Markets & Co., MLV & Co. LLC and Oppenheimer & Co. Inc., each an Agent, which provides that, upon the terms and subject to the conditions and limitations set forth in the ATM Agreement, we may elect, from time to time, to issue and sell shares of common stock having an aggregate offering price of up to \$80,000,000 through any of the Agents. We are not obligated to make any sales of common stock under the ATM Agreement. From July 2017 through December 31, 2018, we sold an aggregate of 5,305,408 shares of common stock pursuant to the ATM Agreement at an average price of \$1.37 per share. On February 4, 2019, we notified the Agents of the termination of the ATM Agreement.

On February 6, 2019, we entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sale Agreement, with Jefferies LLC, as agent, or Jefferies, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to \$50,000,000 from time to time through Jefferies. We are not obligated to make any sales of common stock under the Sale Agreement.

During the six months ended December 31, 2018, we received cash of approximately \$292,000 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% 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 December 31, 2018, total grants obtained from the IIA aggregated to approximately \$27,096,000 and total royalties paid and accrued amounted to \$170,000.

The IIA has supported our activity in the past thirteen years. Our previous program, for the twelfth year, was approved by the IIA in 2017 and relates to a grant of approximately \$1,500,000. The grant was used to cover research and development expenses for the period of January 1, 2017 to December 31, 2017. Our most recent program, for the thirteenth year, was approved by the IIA in 2018 and relates to a grant of approximately \$900,000. The grant was used to cover research and development expenses for the period of January 1, 2018 to December 31, 2018.

As of December 31, 2018, we received total grants of approximately \$3,364,000 in cash from the European Union research and development consortiums pursuant to the Horizon 2020 program.

The currency of our financial portfolio is mainly in U.S. dollars and we use options contracts in order to hedge our exposures to currencies other than the U.S. dollar. For more information, please see Item 7A. - “Quantitative and Qualitative Disclosures about Market Risk” in the 2018 Annual Report on form 10-K for the fiscal year ended June 30, 2018.

We have an effective Form S-3 registration statement, filed under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or the SEC, using a “shelf” registration process. Under this shelf registration process, we may, from time to time, sell common stock, preferred stock and warrants to purchase common stock, and units of two or more of such securities in one or more offerings up to a total dollar amount of \$200,000,000. As of February 6, 2019, we have sold \$7,258,542 of common stock pursuant to the ATM Agreement, which was terminated on February 4, 2019, and \$15,051,000 relating to our public offering which closed on October 31, 2017 pursuant to which we raised aggregate gross proceeds of \$15,051,000 of common stock through the sale of 9,000,000 shares of our common stock at a purchase price of NIS 5.90 (approximately \$1.67 per share), and may be deemed to have sold \$50,000,000 pursuant to the Sale Agreement.

## Outlook

We have accumulated a deficit of \$233,166,000 since our inception in May 2001. We do not expect to generate any revenues from sales of products in the next twelve months. Our cash needs will increase in the foreseeable future. We expect to generate revenues, which in the short and medium terms will unlikely exceed our costs of operations, from the sale of licenses to use our technology or products.

We will be required to obtain additional liquidity resources in order to support the commercialization of our products and maintain our research and development and clinical trials activities.

We are continually looking for sources of funding, including non-diluting sources such as the IIA grants, the European Union grant and other research grants, and sales of our common stock.

As of December 31, 2018, our cash position (cash and cash equivalents and short-term bank deposits) totaled approximately \$14,713,000. We are addressing our liquidity issues by implementing initiatives to allow the

continuation of our activities. Our current operating plan includes various assumptions concerning the level and timing of cash outflows for operating activities and capital expenditures. Our ability to successfully carry out our business plan, which includes a cost-reduction plan should we be unable to raise sufficient additional capital, is primarily dependent upon our ability to (1) obtain sufficient additional capital, (2) enter into license agreements to use or commercialize our products and (3) receive other sources of funding, including non-diluting sources such as the IIA grants, the Horizon 2020 grant and other grants. There are no assurances, however, that we will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of our products.

According to management's estimates, liquidity resources as of December 31, 2018 will be sufficient to maintain our operations into the beginning of the first quarter of fiscal year 2020. Our inability to raise funds to carry out our business plan will have a severe negative impact on our ability to remain a viable company.

#### Off Balance Sheet Arrangements

We have no off balance sheet arrangements.

#### Item 4. Controls and Procedures.

**Evaluation of Disclosure Controls and Procedures** - We maintain a system of disclosure controls and procedures that are designed for the purposes of ensuring that information required to be disclosed in our SEC reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Co-Chief Executive Officers, or Co-CEOs, and our Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

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

**Changes in Internal Control Over Financial Reporting** - There has been no change in our internal control over financial reporting during the second quarter of fiscal year 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

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

During the three months ended December 31, 2018, we issued an aggregate of 73,538 shares of common stock to a consultant for services rendered. We issued these shares pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act.

### Item 5. Other Information.

#### Open Market Sale Agreement

On February 6, 2019, we entered into the Sale Agreement with Jefferies, as agent, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to \$50 million from time to time through Jefferies.

Any sales of shares of common stock pursuant to the Sale Agreement will be made under our currently effective shelf registration statement on Form S-3 (File No. 333-218916), the prospectus contained therein and the prospectus supplement dated and filed on February 6, 2019. Jefferies may sell common stock (A) in privately negotiated transactions with our consent; (B) as block transactions; or (C) by any other method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on The Nasdaq Capital Market or sales made into any other existing trading market for our common stock. Subject to the terms and conditions of the Sale Agreement, Jefferies will use its commercially reasonable efforts to sell the shares of our common stock from time to time, based upon our instructions (including any price, time or size limits or other parameters or conditions that we may impose). We will pay to Jefferies a cash commission of 3.0% of the gross proceeds from the sale of any shares of common stock by Jefferies under the Sale Agreement. We will also reimburse Jefferies for certain specified expenses in connection with entering into the Sale Agreement. We and Jefferies have also provided each other with customary indemnification rights.

We are not obligated to make any sales of common stock under the Sale Agreement and no assurance can be given that we will sell any shares under the Sale Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. The Sale Agreement may be terminated by either party at any time upon 1 trading days’ notice to the other party, or by Jefferies at any time in certain circumstances. In addition, the Sale Agreement will automatically terminate upon the sale of all common stock subject to the Sale Agreement.

The foregoing description of the Sale Agreement is not complete and is qualified in its entirety by reference to the full text of the Sale Agreement, a copy of which is filed as Exhibit 1.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

The legal opinion of Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, relating to the common stock being offered pursuant to the Sale Agreement, is filed as Exhibit 5.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

The above disclosure shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

#### Termination of ATM Agreement

On February 4, 2019, we delivered written notice to the Agents terminating the ATM Agreement. The termination of the ATM Agreement will be effective on February 6, 2019. We have sold an aggregate of 5,305,408 shares of our common stock under the ATM Agreement, for net proceeds of approximately \$6.9 million. No additional shares of our common stock will be sold pursuant to the ATM Agreement. We are not subject to any termination penalties in connection with the termination of the ATM Agreement.

Item 6. Exhibits.

1.1\* Open Market Sale Agreement<sup>SM</sup>, dated February 6, 2019, by and between the Company and Jefferies LLC.

5.1\* Opinion of Zysman, Aharoni, Gayer and Sullivan & Worcester LLP.

23.1\* Consent of Zysman, Aharoni, Gayer and Sullivan & Worcester LLP (included in the opinion filed as Exhibit 5.1).

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

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

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

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

32.2\*\* Certification of Co-Chief Executive Officer pursuant to 18 U.S.C. Section 1350.

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

101 \* The following materials from our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018 formatted in XBRL (eXtensible Business Reporting Language): (i) the Interim Condensed Consolidated Balance Sheets, (ii) the Interim Condensed Consolidated Statements of Operations, (iii) the Interim Condensed Consolidated Statements of Comprehensive Loss, (iv) the Interim Condensed Statements of Changes in Equity, (v) the Interim Condensed Consolidated Statements of Cash Flows, and (vi) the Notes to Interim Condensed Consolidated Financial Statements, tagged as blocks of text and in detail.

\*Filed herewith.

\*\* Furnished herewith.



SIGNATURES

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

PLURISTEM THERAPEUTICS INC.

By: /s/ Zami Aberman

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

Date: February 6, 2019

By: /s/ Yaky Yanay

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

Date: February 6, 2019

By: /s/ Erez Egozi

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

Date: February 6, 2019