# PLURISTEM THERAPEUTICS INC Form 10-Q February 06, 2018

	TATES ES AND EXCHANGE COMMISSION n, D.C. 20549					
Form 10-Q						
(Mark One	)					
QUARTI	ERLY REPORT UNDER SECTION 13 OR 15(d)	OF THE SECURITIES EXCHANGE ACT OF 1934				
For the qua	arterly period ended December 31, 2017					
TRANSI	TION REPORT UNDER SECTION 13 OR 15(d)	OF THE EXCHANGE ACT				
	nsition period fromto					
Commissio	on file number 001-31392					
	EM THERAPEUTICS INC. ne of registrant as specified in its charter)					
Nevada (State or ot	her jurisdiction of incorporation or organization)	98-0351734 (IRS Employer Identification No.)				
	Advanced Technology Park, Building No. 5, Haifa f principal executive offices)	Israel 31905				
011-972-74 (Registrant	4-7108607 's telephone number)					
Securities I		reports required to be filed by Section 13 or 15(d) of the or for such shorter period that the registrant was required quirements 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 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):

Large accelerated filer

Non-accelerated filer (do not check if a smaller reporting company)

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: 110,097,087 shares of common stock issued and outstanding as of February 1, 2018.

## PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of December 31, 2017

(Unaudited)

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of December 31, 2017

## U.S. DOLLARS IN THOUSANDS

(Unaudited)

## **INDEX**

	Page
Interim Condensed Consolidated Balance Sheets	F-2 - F-3
Interim Condensed Consolidated Statements of Operations	F-4
Interim Condensed Consolidated Statements of Comprehensive Loss	F-5
Interim Condensed Statements of Changes in Stockholders' Equity	F-6 - F-7
Interim Condensed Consolidated Statements of Cash Flows	F-8 - F-9
Notes to Interim Condensed Consolidated Financial Statements	F-10 - F-21

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

ASSETS CURRENT ASSETS:	Note	December 31, 2017 Unaudited	-
Cash and cash equivalents Short-term bank deposits Restricted cash and short-term bank deposits Marketable securities Accounts receivable from the Israeli Innovation Authority ("IIA") Other current assets Total current assets	3	\$ 8,581 15,975 566 10,736 172 1,044 37,074	1,036 1,315
LONG-TERM ASSETS:			
Long-term deposits and restricted bank deposits Severance pay fund Property and equipment, net Other long-term assets Totallong-term assets		403 856 6,367 33 7,659	403 804 7,277 34 8,518
<u>Total</u> assets		\$ 44,733	\$37,534

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)

LIABILITIES AND STOCKHOLDERS' EQUITY	Note	December 31, 2017 Unaudited	June 30, 2017
CURRENT LIABILITIES			
Trade payables Accrued expenses Other accounts payable Total current liabilities		\$1,808 1,714 2,275 5,797	\$1,966 1,465 1,983 5,414
LONG-TERM LIABILITIES			
Accrued severance pay Other long-term liabilities Total long-term liabilities COMMITMENTS AND CONTINGENCIES	5	1,078 897 1,975	940 929 1,869
STOCKHOLDERS' EQUITY	6		
Share capital: Common stock \$0.00001 par value per share: Authorized: 200,000,000 shares Issued and outstanding: 109,337,556 shares as of December 31, 2017, 96,938,789 shares as of June 30, 2017 Additional paid-in capital Accumulated deficit Other comprehensive income Total stockholders' equity		1 236,767 (205,185) 5,378 36,961	1 217,822 (189,571) 1,999 30,251
Total liabilities and stockholders' equity		\$44,733	\$37,534

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements. F-3

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

		Six months ended December 31			Three mont	ended			
	Note	2017		2016		2017	Í	2016	
Revenues	2f	\$50		_		\$50		-	
Cost of revenues		(2	)	-		(2	)	-	
Gross profit		48		-		48		-	
Operating Expenses:									
Research and development expenses		(11,451	)	(11,512	)	(6,259	)	(5,481	)
Less: participation by the IIA and other parties		1,136		1,312		621		279	
Research and development expenses, net		(10,315	)	(10,200	)	(5,638	)	(5,202	)
General and administrative expenses, net		(5,683	)	(3,010	)	(2,920	)	(1,446	)
Other income	7	43		-		43		-	
Operating loss		(15,907	)	(13,210	)	(8,467	)	(6,648	)
Financial income, net		293		276		238		38	
Net loss for the period		\$(15,614	)	\$(12,934	)	\$(8,229	)	\$(6,610	)
Loss per share: Basic and diluted net loss per share		\$(0.15	)	\$(0.16	)	\$(0.08	)	\$(0.08	)
Weighted average number of shares used in computing basic and diluted net loss per share		101,224,32	5	80,856,21	19	105,130,1	91	81,038,8	79

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements. F-4

## PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

# INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED) U.S. Dollars in thousands

	Six month	s ended	Three ended	months
	December	31,	Decen	nber 31,
	2017	2016	2017	2016
Net loss	\$(15,614)	\$(12,934	\$ (8,22	9) \$(6,610)
Other comprehensive income (loss), net:				
Unrealized gain (loss) on available-for-sale marketable securities, net	4,307	(999	) 5,440	(1,585)
Reclassification adjustment of available-for-sale marketable securities				
losses realized in net loss, net	(928)	(20	) (1,00	(16)
Other comprehensive income (loss)	3,379	(1,019	) 4,434	1 (1,601)
Total comprehensive loss	\$(12,235)	\$(13,953	(3,79)	5) \$(8,211)

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements. F - 5

## 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)

				Accumulate	d		
			Additional	Other		Total	
	Common Sto	ock	Paid-in	Comprehens	siveAccumulated	d Stockholders'	
				Income			
	Shares	Amoun	t 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							
employees, directors							
and non-employee consultants	1,030,952	(* )	907	-	-	907	
Other comprehensive loss, net	-	-	-	(1,019	) -	(1,019 )	
Net loss	-	-	-	-	(12,934	) (12,934 )	
Balance as of December 31, 2016	01 205 051	Φ 1	ф 100 242	<b>D</b> 461	Φ (1 <b>7</b> 4 (01	)	
(unaudited)	81,305,951	\$ 1	\$199,343	\$ 461	\$ (174,691	) \$ 25,114	

(\*) Less than \$1

The accompanying notes are an integral part of the unaudited interim condensed consolidated financial statements. F-6

## 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)

	C C	1	Additional			Total
	Common Stoc		Paid-in	ComprehensiveAccumulated		
	Shares		nt Capital	Income	Deficit	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 CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) U.S. Dollars in thousands

	Six mon Decemb 2017			
CASH FLOWS FROM OPERATING ACTIVITIES:	2017		2010	
Net loss	\$(15,61	4)	\$(12,93	4)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	1,023		1,110	
Gain from sale of property and equipment, net	-		(4	)
Accretion of discount, amortization of premium and changes in accrued interest of marketable				
securities	12		(154	)
Gain from sale of investments of available-for-sale marketable securities	(928	)	(20	)
Other-than-temporary loss of available-for-sale marketable securities	850		-	
Stock-based compensation to employees, directors and non-employees consultants	3,108		907	
Decrease in accounts receivable from the IIA	864		1,941	
Decrease (increase) in other current and long-term assets	272		(105	)
Increase (decrease) in trade payables	(86	)	160	
Increase (decrease) in other accounts payable, accrued expenses and other long-term liabilities	421		(588	)
Increase in interest receivable on short-term deposits	(28	)	-	
Linkage differences and interest on short and long-term deposits and restricted bank deposits	2		(1	)
Accrued severance pay, net	86		(11	)
Net cash used by operating activities	\$(10,01	8)	\$(9,699	)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment	\$(185	)	\$(273	)
Proceeds from sale of property and equipment	-		6	
Repayment of (investment in) short-term deposits	(9,721	)	8,542	
Proceeds from sale of available-for-sale marketable securities	9,010		3,813	
Proceeds from redemption of available-for-sale marketable securities	9		280	
Investment in available-for-sale marketable securities	(1,146	)	(1,562	. )
Net cash provided by (used in) investing activities	-		\$10,800	

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 monti ended De 31,	
	2017	2016
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds related to issuance of common stock, net of issuance costs	\$14,672	\$-
Exercise of warrants and options	1,165	4
Proceeds with respect to BIRD liability	88	-
Net cash provided by financing activities	\$15,925	\$4
Increase in cash and cash equivalents	3,874	1,111
Cash and cash equivalents at the beginning of the period	4,707	6,223
Cash and cash equivalents at the end of the period	\$8,581	\$7,334
(a) Supplemental disclosure of cash flow activities: Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$6	\$16
(b) Supplemental disclosure of non-cash activities:		
Purchase of property and equipment on credit	\$16	\$36

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".

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 \$205,185 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of December 31, 2017, the Company's total stockholders' equity amounted to \$36,961.

During the six month period ended December 31, 2017, the Company incurred operating losses of \$15,907 and its negative cash flow from operating activities was \$10,018. 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, 2017, the Company's cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$35,292. 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, 2017, together with the proceeds received from the sale of shares of CHA Biotech Co. Ltd. ("CHA") after the balance sheet date (See Note 1c) and the issuance of shares under the At Market Issuance Sales Agreement (See Note 6), will be sufficient to maintain the Company's operations into the fourth quarter of the Company's fiscal year 2019. 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.

#### c. License Agreement:

### **CHA Agreement**

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

#### PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 1:-GENERAL (CONT.)

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

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

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

The CHA Agreement contains customary termination provisions, including in the event the parties do not reach an agreement upon development plan for conducting the clinical trials. Upon termination of 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.

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 ("ASC") 320, "Investments - Debt and Equity Securities". The fair value of the remaining investment in CHA's shares as of December 31, 2017, is approximately \$8,440.

In January 2018, subsequent to the balance sheet date, the Company sold its remaining investment in CHA, for aggregate net proceeds of approximately \$10,500, representing a net gain of \$6,200 that was recognized as financial income.

## 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).

#### 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.)

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, 2017.

Operating results for the three and six month periods ended December 31, 2017, are not necessarily indicative of the results that may be expected for the year ending June 30, 2018.

## 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 ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"). Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly; and
- Level 3 Unobservable inputs for the asset or liability.

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

#### 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.)

#### 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. 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, 2017 the fair value of the options contracts were approximately\$ 77, presented in "other current assets" (see Note 4). The net losses recognized in "Financial income, net" during the three and six month periods ended December 31, 2017 and 2016, were )\$(74, (\$217) and )\$(131, (\$66), respectively.)

#### f. Recently Adopted Accounting Standards

#### ASC Topic 606, "Revenue from Contracts with Costumers" (ASC 606):

The Company adopted ASC 606 on July 1, 2017, using the modified retrospective transition method. Prior periods were not retrospectively adjusted. As the Company did not have any contracts with customers that were not completed as of June 30, 2017, the adoption of ASC 606 did not, and does not, have a material impact on the Company's consolidated financial statements, including the presentation of revenues in our consolidated statements of operations upon adoption.

## Revenue Recognition from sales of products:

Revenues are recognized when control of the promised goods is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods.

The Company's contract with the customer includes one type of product and thus has only one performance obligation, which is the transfer of control of the product. The Company's PLX cells have an alternative use and, as such, the performance obligation is considered to be satisfied at a point in time where the customer obtains control over the product.

#### 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.)

## Accounting Standards Update ("ASU") 2017-11 - Earnings Per Share (Topic 260);

Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU No. 2017-11"):

In July 2017, the Financial Accounting Standards Board ("FASB") issued ASU No. 2017-11. The ASU was issued to address the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. The ASU, among other things, eliminates the need to consider the effects of down round features when analyzing convertible debt, warrants and other financing instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The Company was an early adopter of ASU No. 2017-11 as of July 1, 2017. The adoption of ASU No. 2017-11 does not have a material impact on the Company's consolidated financial statements and related disclosures.

## g. Recently Issued Accounting Pronouncements

## ASU 2016-02 - Leases (Topic 842):

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

## ASU 2016-15 - Statement of Cash Flows (Topic 230):

In August 2016, the 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 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 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 3:- MARKETABLE SECURITIES

As of December 31, 2017, all of the Company's marketable securities were classified as available-for-sale.

	Decemb	ember 31, 2017			June 30, 2017					
		Gross	Gros	S			Gross	Gross		
	Amortiz	zednrealize	edinrea	al <b>Othe</b> r-th	an- <b>Tean</b> porar	yAmortize	edunrealiz	edınreali	iz <b>@t</b> her-th	an- <b>Fean</b> porary
	cost	gain	loss	impairm	ent value	cost	gain	loss	impairm	entvalue
Available-for-sale -										
matures within one										
year:										
Stock and index	Φ.C. <b>2</b> 000	Φ. <b>5. 27</b> 0	Ф	Φ (050	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	ф11 OOO	Φ 2 01 4	ф ( <b>47</b> )	Φ (7.67	) #12 100
linked notes	\$6,208	\$5,378	\$ -	\$ (850	) \$10,736	\$11,988	\$2,014	\$ (47	) \$ (767	) \$13,188
Government debentures – fixed										
interest rate						157	1			158
Corporate debentures	-	-	-	-	-	137	1	-	-	136
<ul><li>fixed interest rate</li></ul>	_	_	_	_	_	47	1	_	_	48
- fixed interest rate	\$6,208	\$5,378	\$ -	\$ (850	) \$10,736			\$ (47	) \$ (767	) \$13,394
Available-for-sale -	Ψ0,200	Ψ5,570	Ψ	Ψ (050	, φ10,730	Ψ12,172	Ψ2,010	Ψ(17	) ψ (101	) 413,371
matures after one										
year through five										
years:										
Government										
debentures – fixed										
interest rate	-	-	-	-	-	468	23	-	-	491
Corporate debentures										
<ul> <li>fixed interest rate</li> </ul>	-	-	_	-	-	1,255	7	(1	) -	1,261
	\$-	\$ -	\$ -	\$ -	\$-	\$1,723	\$30	\$ (1	) \$ -	\$1,752
Available-for-sale -										
matures after five										
years through ten										
years: Corporate debentures										
<ul><li>fixed interest rate</li></ul>	_	_	_	_	_	17	1	_	_	18
Tixed interest rate	\$-	\$-	\$ -	\$ -	\$-	\$17	\$1	\$ -	\$ -	\$18
Total	\$6,208	\$5,378	\$ -	\$ (850	) \$10,736			т	\$ (767	) \$15,164
F - 15										
1 - 1 <i>J</i>										

## 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 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.

The Company recognized other-than-temporary impairment losses on outstanding securities during the six month period ended December 31, 2017 of \$850.

During January 2018, after the balance sheet date, the Company sold all its investment in its marketable securities.

#### NOTE 4:- FAIR VALUE OF FINANCIAL INSTRUMENTS

	Decemb 2017	per 31,			
	(Unaudi	ited)	June 30, 2017		
	Level	Level		Level	
	1	2	Level 1	2	
Marketable securities	\$8,440	\$2,296	\$10,523	\$4,641	
Foreign currency derivative instruments	-	77	-	295	
Total financial assets	\$8,440	\$2,373	\$10,523	\$4,936	

#### NOTE 5: - COMMITMENTS AND CONTINGENCIES

a. As of December 31, 2017, an amount of \$965 of cash was pledged by the Subsidiary to secure the derivatives and hedging transactions, credit line and bank guarantees.

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, 2017, total grants obtained from the IIA aggregated to approximately \$25,974 and total royalties paid and accrued amounted to \$168. As of December 31, 2017, the Company's contingent liability in respect to royalties to the IIA amounted to \$25,806, not including LIBOR interest as described above.

#### PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

# NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share amounts)

## NOTE 5: - COMMITMENTS AND CONTINGENCIES (CONT.)

In July 2017, the Company was awarded an additional "Smart Money" grant of approximately \$229 from Israel's c. Ministry of Economy and Industry to facilitate certain marketing and business development activities in the Chinese market, including Hong Kong, with its advanced cell therapy products.

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.

Through December 31, 2017, the aggregate amount of grants obtained from the Smart Money program was approximately \$9. No royalties were paid or accrued. As of December 31, 2017, the Company's contingent liability with respect to royalties for the "Smart Money" program was \$9.

In September 2017, the Company signed an agreement with the Tel-Aviv Sourasky Medical Center (Ichilov d. 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.

#### 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, 2017, the Company sold 834,040 shares of common stock under the ATM Agreement at an average price of \$1.33 per share. The Company raised approximately \$1,026, net of issuance expenses of \$80, under 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 b. 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.

#### 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.)

Through the six month period ended December 31, 2017, a total of 828,703 warrants were exercised by investors at c.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.

d. Options, warrants, restricted stock ("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". 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, 2017			
	(Unaudited)	)		
			Weighted	
			Average	
		Weighted	Remaining	Aggregate
		Average	Contractual	Intrinsic
		Exercise	Terms (in	Value
	Number	Price	years)	Price
Options outstanding at beginning of period	815,650	\$ 2.98		
Options exercised	(5,000)	\$ 1.04		
Options forfeited	(450,150)	\$ 4.86		
Options outstanding at end of the period	360,500	\$ 0.643	0.820	\$ 266
Options exercisable at the end of the period	360,500	\$ 0.643	0.820	\$ 266
Options vested	360,500	\$ 0.643	0.820	\$ 266

Six months ended December 31, 2017

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 December 31, 2017. 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.)

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

## 2. Options to non-employees:

The Company accounts for its options to non-employees under the fair value method in accordance with ASC 718, "Compensation—Stock Compensation". 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, 2017 (Unaudited)

		Weighted	
		Average	
	Weighted	Remaining	Aggregate
	Average	Contractual	Intrinsic
	Exercise	Terms (in	Value
Number	Price	years)	Price
177,200	\$ 0.72		
47,400	\$ 0.00		
(15,000)	\$ 4.38		
209,600	\$ 0.30	5.46	\$ 275
173,825	\$ 0.36	4.54	\$ 209
209,600	\$ 0.30	5.46	\$ 275
	177,200 47,400 (15,000) 209,600 173,825	Average Exercise  Number Price 177,200 \$ 0.72 47,400 \$ 0.00 (15,000) \$ 4.38 209,600 \$ 0.30  173,825 \$ 0.36	Number       Price       years         177,200       \$ 0.72         47,400       \$ 0.00         (15,000)       \$ 4.38         209,600       \$ 0.30         5 0.36       4.54

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

			Three	
	Six months		months	
	ended		ended	
	December		December	
	31,		31,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	
Research and development expenses	\$6	\$ 3	\$3	\$ 3
General and administrative expenses	\$ 28	\$ 14	\$ 13	\$ 14
	\$ 34	\$ 17	\$ 16	\$ 17

#### 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 ("RS") and restricted stock units ("RS") to employees, directors and consultants (cont.):

## 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 its 2005 and 2016 incentive option plans for the six month period ended December 31, 2017 (Unaudited) is as follows:

	Number
Unvested at the beginning of period	6,064,901
Granted	3,025,800
Forfeited	(138,579)
Vested	(1,357,944)
Unvested at the end of the period	7,594,178
Expected to vest after December 31, 2017	7,394,200

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

	Six months		Three months	
	ended		ended	
	December 31,		December 31,	
	2017	2016	2017	2016
	(Unaudited)			
	(Unaudi	ited)	(Unaudi	ted)
Research and development expenses			`	
Research and development expenses General and administrative expenses	\$331	\$210	\$187	

Unamortized compensation expenses related to RS and RSUs granted to employees and directors to be recognized over an average time of approximately 3.5 years are approximately \$7,822.

#### 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 ("RS") and restricted stock units ("RSU") to employees, directors and consultants (cont.):

#### 4.RS and RSUs to consultants:

The following table summarizes the activity related to unvested RS and RSUs granted to consultants under its 2005 and 2016 incentive option plan for the six month period ended December 31, 2017, (Unaudited) is as follows:

	Number
Unvested at the beginning of period	42,500
Granted	513,180
Vested	(373,080)
Unvested at the end of the period	182,600

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

			Three	
	Six months ended December		months ended December	
	31,		31,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	
Research and development expenses	\$3	\$7	\$3	\$3
General and administrative expenses	173	234	122	125
	\$176	\$241	\$125	\$128

#### **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 aim to reward and honor Israeli employers who demonstrate and promote gender equality in employment.

#### **NOTE 8:-SUBSEQUENT EVENTS**

During January 2018, the Company sold 626,800 shares of common stock under the ATM Agreement at an average price of \$1.57 per share.

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 stother 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 joint venture, described in the overview below, 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 into 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, 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. A pivotal, multinational clinical trial is currently being conducted with our PLX-PAD product candidate in CLI. In addition, pivotal, multinational clinical trial is planned for our PLX-PAD product candidate in femoral neck fractures. The National Institutes of Health's National Institute of Allergy and Infectious Diseases, or NIAID, recently completed a dose selection trial with PLX-R18 in the hematologic component of ARS and a pivotal study is planned under the U.S. Food and Drug Administration, or FDA, animal rule once funding will be secured for this project. Each of these indications is a severe unmet medical need.

PLX cells are derived from a class of placental cells that are harvested from donated placentas 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 FDA's current Good Manufacturing Practice requirements and has been approved by the European, Japanese and Israeli regulatory authorities for production of PLX-PAD for late stage trials and marketing. 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 approval 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 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 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. We are pursuing these accelerated pathways for PLX-PAD in CLI and femoral neck fracture. Our second product candidate, PLX R18, is under development in the United States for ARS via the Animal Rule regulatory pathway, which may result in approval without the prior performance of human efficacy trials. We expect to demonstrate a real-world impact and value from our pipeline, technology platform and commercial-scale manufacturing capacity.

In May 2015, we announced that the PLX-PAD cell program in CLI had been selected for the Adaptive Pathways pilot project of the European Medicines Agency, or EMA. During fiscal year 2017, the FDA, and several EU regulatory agencies 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 is being conducted in the United States and Europe.

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 (estimated) trial. An interim efficacy analysis is planned to be conducted based on data from the first 125 patients. If these trials yield positive results, they could lead to early conditional marketing approval in Europe.

In September, 2017, we announced that the FDA has granted a fast track designation to our ongoing Phase III study of PLX-PAD cells for the treatment of CLI in patients ineligible for revascularization. The FDA's fast track designation is a process designed to facilitate the development and expedite the review of drug to treat serious conditions and unmet medical needs. With fast track designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

In August 2016, our CLI program in the European Union was awarded a Euro 7,600,000 (approximately \$9,100,000) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD in CLI will be a collaborative project carried out by an international consortium led by the Berlin-Brandenburg Center for Regenerative Therapies together with us and with participation of additional third parties. The grant will cover a significant portion of the CLI program costs. An amount of Euro 1,900,000 (approximately \$2,300,000) is a direct grant allocated to us for manufacturing and other costs, and we also expect to have direct benefit from cost savings resulting from grant amounts allocated to the other consortium members. In July 2017, the consortium amended the consortium agreement, pursuant to which the original grant allocation has been amended such that we will receive an additional direct grant of Euro 1,000,000 (approximately \$1,200,000). The additional direct grant was allocated to us from the total amount of the original grant.

In December 2016, we announced that we signed a binding term sheet with Sosei Corporate Venture Capital Ltd., or Sosei CVC, for the establishment of a new Japanese corporation, or NewCo, for the clinical development and commercialization of our PLX-PAD cell therapy product in Japan for CLI. The parties plan to establish NewCo in Japan, in which we will own 35% of the equity in return for our contribution of a perpetual license to commercialize PLX-PAD for CLI in Japan. All proprietary rights related to PLX-PAD will be exclusively owned by us. Sosei CVC's investment fund, Sosei RMF1, together with additional Japanese investors, will raise and invest approximately \$11 million, equivalent to approximately \(\frac{\frac{1}}{1.3}\) billion, in return for ownership of 65% of NewCo. We are still in discussions with Sosei CVC and other related investors in order to finalize the terms of a definitive agreement. In December 2015, we reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency 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.

In January 2018, we announced that the FDA cleared our Expanded Access Program, or EAP, for the use of our PLX-PAD cell treatment in patients with CLI. EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need. As part of the EAP, our PLX-PAD cell therapy will be made available to a limited number of Rutherford Category 5 CLI patients in the United States who are unsuitable for revascularization and cannot take part in the our ongoing Phase III clinical study.

In January 2017, we announced that we had completed enrollment of all 172 patients in the randomized, double blind, placebo controlled, multinational Phase II intermittent claudication, or IC, clinical trial. We anticipate data readouts in second quarter of 2018.

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 EMA, confirmed that this indication would also be eligible for the Adaptive Pathways project.

In September 2017, our Phase III study of PLX-PAD cells to support recovery following surgery for femoral neck fracture was awarded a Euro 7,400,000 (approximately \$8,900,000) grant. The grant is part of the European Union's Horizon 2020 program. The Phase III study of PLX-PAD to support recovery following surgery for femoral neck fractures will be a collaborative project carried out by an international consortium led by Charite Universitätsmedizin Berlin, together with us, and with participation of additional third parties. The grant will cover a significant portion of the project costs. An amount of Euro 2,400,000 (approximately \$2,900,000) is a direct grant allocated to us for manufacturing and other costs, and we also expect to have a direct benefit from cost savings resulting from grant amounts allocated to the other consortium members.

In November, 2017, we announced that the U.S. Patent and Trademark Office issued a patent titled, "Skeletal muscle regeneration using mesenchymal system cells". This key patent, which has already been granted to us in Europe, Hong Kong and Israel, addresses the use of mesenchymal stem cells for skeletal muscle regeneration used either directly

after, or shortly after, post-surgical muscle injury.

In May 2017, we announced promising results of our non-human primates, or NHPs, pilot study for PLX-R18 as a treatment for ARS. The study, conducted and funded by the NIAID, was designed to assess the safety and efficacy of PLX-R18 following intramuscular injection into irradiated and non-irradiated NHPs. Efficacy measures included survival as well as level of bone marrow function, which is affected by exposure to high levels of radiation as may occur in a nuclear accident or attack. These data will help support a pivotal study designed to meet the requirements for a Biologics License Application submission under the FDA's Animal Rule regulatory pathway.

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. In August 2017, we announced that a pilot study of our PLX-R18 cell therapy will be initiated by the U.S. Department of Defense's Armed Forces Radiobiology Research Institute, part of the Uniformed Services University of Health Sciences. The study will examine the effectiveness of PLX-R18 as a treatment for ARS prior to, and within the first 24 hours of exposure to radiation.

In October 2017, we announced that the FDA granted us an orphan drug designation for our PLX-R18 cell therapy for the prevention and treatment of ARS.

PLX R18 is also under development in a Phase I trial in the United States and Israel for incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT. We initiated the trial in fiscal year 2017 in the United States. In October 2017, we received an approval from the Israeli Ministry of Health to initiate this Phase I trial in Israel as well.

In October 2017, the nTRACK, a collaborative project carried out by an international consortium led by LEITAT, was awarded a Euro 6,800,000 (approximately \$8,000,000) non-royalty bearing grant. An amount of Euro 500,000 (approximately \$600,000) is a direct grant allocated to us. We also expect to benefit from cost savings resulting from grant amounts allocated to the other consortium members.

In September 2017, we signed an agreement with Tel Aviv Sourasky Medical Center (Ichilov Hospital) to conduct a Phase I/II trial of PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-Versus-Host-Disease. This trial is an investigator initiated study. As such, Tel Aviv Sourasky Medical Center will support the study and will be responsible for its design and implementation.

In January 2018, we announced the publication of a peer-reviewed article in a journal which examined the effect of PLX-immune cells on the proliferation of over 50 lines of human cancerous cells. Data showed that the PLX-immune cells exhibited an anti-proliferative effect on a wide range of human cancer cell types, with a strong inhibitory effect on various lines of breast, colorectal, kidney, liver, lung, muscle and skin cancers. We have also conducted a pre-clinical study of female mice harboring human triple negative breast cancer. In this study, the results showed a statistically significant reduction in tumor size as well as complete tumor remission in 30% of treated recipients.

RESULTS OF OPERATIONS – SIX AND THREE MONTHS ENDED DECEMBER 31, 2017 COMPARED TO SIX AND THREE MONTHS ENDED DECEMBER 31, 2016.

#### Revenues

Revenues for the six and three month periods ended December 31, 2017 were \$50,000, versus no revenues generated in the six and three month period ended December 31, 2016. All revenues in the period ended December 31, 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 months ended December 31, 2017 increased by 1% from \$10,200,000 for the six months ended December 31, 2016 to \$10,315,000. This increase is mainly attributed to: (1) an increase in payroll expenses related to differences in exchange rates, an increase in the number of employees and increases in average salaries, and (2) a decrease in IIA participation (\$3,300,000 was approved in calendar year 2016 compared to \$1,500,000 that was approved in calendar year 2017). The increase was partially offset by a decrease in subcontractors' expenses related to clinical studies such as our CLI and IC studies. In addition, it was also offset by participation of \$485,000 of 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, 2017 increased by 8% from \$5,202,000 for the three months ended December 31, 2016 to \$5,638,000. This increase is mainly attributed to an increase in materials consumption and an increase in payroll expenses, consisting of an increase in the number of employees, increases in average salaries and differences in exchange rates. The increase was partially offset by a decrease in subcontractors' expenses related to clinical studies such as our CLI and IC studies. In addition, it was also offset by participation of \$317,000 of 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 months ended December 31, 2017 increased by 89% from \$3,010,000 for the six months ended December 31, 2016 to \$5,683,000, mainly due to: (1) an increase in stock-based compensation expenses related to the amount of restricted stock units granted, (2) an increase in payroll expenses related to an increase in the number of employees, increases in average salaries and differences in exchange rates, and (3) an increase in corporate activities expenses.

General and administrative expenses for the three months ended December 31, 2017 increased by 102% from \$1,446,000 for the three months ended December 31, 2016 to \$2,920,000, mainly due to: (1) an increase in stock-based compensation expenses related to the amount of restricted stock units granted, (2) an increase in payroll expenses related to an increase in the number of employees, increases in average salaries and differences in exchange rates, and (3) an increase in corporate activities expenses.

#### Financial Income, Net

Financial income, net, increased from a net income of \$276,000 for the six months ended December 31, 2016 to a net income of \$293,000 for the six months ended December 31, 2017. This increase is mainly attributable to increased income from exchange rates, since during the six months ended December 31, 2017, there was a decrease of 0.8% of the U.S. dollar against the New Israeli Shekel, or NIS, compared to a decrease of 0.03% of the U.S. dollar against the NIS during the six months ended December 31, 2016, and from our hedging instruments related to the strength of the U.S. dollar against the NIS. The increase was partially offset by lower income from our marketable securities mainly attributable to an expense of \$850,000 resulting from other-than-temporary impairment loss recognized in the six

months ended December 31, 2017.

Financial income, net, increased from a net financial income of \$38,000 for the three months ended December 31, 2016 to a net financial income of \$238,000 for the three months ended December 31, 2017. This increase is mainly attributable to increased income from exchange rates, since during the three months ended December 31, 2017, there was a decrease of 1.8% of the U.S. dollar against the NIS compared to an increase of 2.3% of the U.S. dollar against the NIS during the three months ended December 31, 2016, and from our hedging instruments related to the strength of the U.S. dollar against the NIS.

This increase was partially offset by lower income mainly attributable to the sale of our marketable securities which occurred in the three months ended September 30, 2017.

#### Net Loss

Net loss for the six and three month periods ended December 31, 2017 was \$15,614,000 and \$8,229,000, respectively, as compared to net loss of \$12,934,000 and \$6,610,000 for the six and three month periods ended December 31, 2016, respectively. The changes were mainly due to the increases in general and administrative expenses, as described above. Net loss per share for the six and three month periods ended December 31, 2017 was \$0.15 and \$0.08, respectively, as compared to \$0.16 and \$0.08 for the six and three month periods ended December 31, 2016.

For the six and three month periods ended December 31, 2017 and December 31, 2016, we had weighted average shares of common stock outstanding of 101,224,325, 105,130,191 and 80,856,219, 81,038,879, 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 offerings we conducted in January and 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 and warrants.

## Liquidity and Capital Resources

As of December 31, 2017, our total current assets were \$37,074,000 and total current liabilities were \$5,797,000. On December 31, 2017, we had a working capital surplus of \$31,277,000, stockholders' equity of \$36,961,000 and an accumulated deficit of \$205,185,000. 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 and funds from grants from the IIA, Israel's Ministry of Economy, European Union and other research grants.

Our cash and cash equivalents as of December 31, 2017 amounted to \$8,581,000 compared to \$7,334,000 as of December 31, 2016, and compared to \$4,707,000 as of June 30, 2017. Cash balances changed in the six months ended December 31, 2017 and 2016 for the reasons presented below.

Operating activities used cash of \$10,018,000 in the six months ended December 31, 2017, compared to \$9,699,000 in the six months ended December 31, 2016. Cash used in operating activities in the six months ended December 31, 2017 and 2016 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, Israel's Ministry of Economy and Horizon 2020.

Investing activities used cash of \$2,033,000 in the six months ended December 31, 2017, compared to cash provided of \$10,806,000 for the six months ended December 31, 2016. The investing activities in the six months ended December 31, 2017 consisted primarily of \$9,721,000 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. The investing activities in the six months ended December 31, 2016 consisted primarily of the withdrawal of \$8,542,000 of short term deposits and \$4,093,000 provided from the sale and redemption of marketable securities, offset by investment of \$1,562,000 in marketable securities and payments of \$273,000 related to investment in property and equipment.

Financing activities generated cash of \$15,925,000 during the six months ended December 31, 2017, compared to \$4,000 for the six months ended December 31, 2016. 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 exercises of options by employees. The cash generated in the six months ended

December 31, 2016 from financing activities was related to exercises of options by employees.

On October 31, 2017, we completed a public offering in Israel, pursuant to our existing shelf registration statement in the United States and a shelf registration statement filed in Israel, pursuant to which we raised aggregate gross proceeds of \$15,051,000 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). The net proceeds, after deducting fees and expenses related to the offering, were \$13,646,000.

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. During the six month period ended December 31, 2017, we sold an aggregate of 834,040 shares of common stock pursuant to the ATM Agreement at an average price of \$1.33 per share.

On January 8, 2018, we sold our entire holdings in CHA Biotech Co. Ltd, or CHA, consisting of 400,368 shares of CHA, on the open market for aggregate net proceeds of approximately \$10,500,000, representing a net gain to us of \$6,200,000 million.

During the six months ended December 31, 2017, we received cash of approximately \$1,504,000 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, 2017, total grants obtained from the IIA aggregated to approximately \$25,974,000 and total royalties paid and accrued amounted to \$168,000.

The IIA has supported our activity in the past twelve years. Our last 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.

As of December 31, 2017, we received total grants of approximately \$1,566,000 in cash from the European Union research and development consortium under our CLI program in the Horizon 2020.

During the six months ended December 31, 2017, we received cash of approximately \$50,000 from a third party from the sale of our PLX cells for research use.

During the six months ended December 31, 2017, we were awarded approximately \$43,000 (NIS 150,000) by the Israeli Ministry of Labor, Social Affairs and Social Services related to "Equal Employment" program which aims to reward and honor Israeli employers who demonstrate and promote gender equality in employment.

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 our Annual Report on form 10-K for the fiscal year ended June 30, 2017.

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, 2018, we have been deemed to have sold \$80,000,000 pursuant to our existing shelf under our ATM Agreement and \$15,051,000 of gross proceeds relating to our public offering of

9,000,000 shares of our common stock.

#### Outlook

We have accumulated a deficit of \$205,185,000 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, 2017, our cash position (cash and cash equivalents, short-term bank deposits and marketable securities) totaled approximately \$35,292,000. 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) entering 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.

During January 2018, we sold 626,800 additional shares of common stock under the ATM Agreement at an average price of \$1.57 per share for aggregate gross proceeds of \$986,000.

According to management's estimates, liquidity resources as of December 31, 2017, together with the proceeds received from the sale of CHA shares and the issuance of additional shares under the ATM Agreement through January 2018, will be sufficient to maintain our operations into the fourth quarter of fiscal year 2019. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the three months ended December 31, 2017, we issued an aggregate of 30,000 shares of common stock to a consultant for services rendered.

The above issuance was exempt under Section 4(a)(2) of the Securities Act.

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 2018 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 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.

The following materials from our Quarterly Report on Form 10-Q for the quarter ended December 31, 2017 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 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, 2018

By: /s/ Yaky Yanay

Yaky Yanay, Co-Chief Executive Officer and President

(Principal Executive Officer) Date: February 6, 2018

By: /s/ Erez Egozi

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

Date: February 6, 2018