

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, 2019**

☐ 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.00001	PSTI	Nasdaq Capital Market

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 filer, a 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 ☐

Emerging growth company ☐

Accelerated filer ☒

Smaller reporting 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: 17,861,541 shares of common stock issued and outstanding as of February 1, 2020.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

As of December 31, 2019

(Unaudited)

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

As of December 31, 2019

U.S. DOLLARS IN THOUSANDS

(Unaudited)

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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	<u>Note</u>	<u>December 31, 2019</u>	<u>June 30, 2019</u>
		<u>Unaudited</u>	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 7,300	\$ 4,106
Short-term bank deposits		8,780	19,599
Restricted cash and short-term bank deposits		571	692
Other current assets		2,576	1,974
<u>Total</u> current assets		<u>19,227</u>	<u>26,371</u>
LONG-TERM ASSETS:			
Long-term deposits and restricted bank deposits		409	398
Severance pay fund		671	693
Property and equipment, net		3,067	3,838
Operating lease right-of-use asset	3	1,484	-
Other long-term assets		2	10
<u>Total</u> long-term assets		<u>5,633</u>	<u>4,939</u>
<u>Total</u> assets		<u>\$ 24,860</u>	<u>\$ 31,310</u>

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

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	<u>Note</u>	<u>December 31, 2019</u>	<u>June 30, 2019</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		\$ 1,857	\$ 2,281
Accrued expenses		2,549	3,744
Operating lease liability, current	3	964	-
Other accounts payable		1,621	2,133
<u>Total</u> current liabilities		<u>6,991</u>	<u>8,158</u>
LONG-TERM LIABILITIES			
Accrued severance pay		920	950
Other long-term liabilities		-	381
Operating lease liability	3	1,039	-
<u>Total</u> long-term liabilities		<u>1,959</u>	<u>1,331</u>
COMMITMENTS AND CONTINGENCIES	4		
STOCKHOLDERS' EQUITY			
Share capital:	5		
Common stock \$0.00001 par value per share: Authorized: 30,000,000 shares Issued and outstanding: 16,934,417 shares as of December 31, 2019, 15,082,852 shares as of June 30, 2019		(*)	(*)
Additional paid-in capital		280,423	272,825
Accumulated deficit		(264,513)	(251,004)
<u>Total</u> stockholders' equity		<u>15,910</u>	<u>21,821</u>
<u>Total</u> liabilities and stockholders' equity		<u>\$ 24,860</u>	<u>\$ 31,310</u>

(*) Less than \$1

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Six months ended December 31		Three months ended December 31,	
	2019	2018	2019	2018
Revenues	\$ 23	\$ 54	\$ 23	\$ 50
Cost of revenues	(1)	(2)	(1)	(2)
Gross profit	22	52	22	48
Operating Expenses:				
Research and development expenses	(11,398)	(15,197)	(5,572)	(7,432)
Less: participation by the Israeli Innovation Authority (IIA), Horizon 2020 and other parties	1,376	2,177	932	1,176
Research and development expenses, net	(10,022)	(13,020)	(4,640)	(6,256)
General and administrative expenses, net	(3,563)	(4,333)	(1,750)	(2,123)
Operating loss	(13,563)	(17,301)	(6,368)	(8,331)
Financial income (expense), net	54	(168)	(2)	(352)
Net loss for the period	<u>\$ (13,509)</u>	<u>\$ (17,469)</u>	<u>\$ (6,370)</u>	<u>\$ (8,683)</u>
Loss per share:				
Basic and diluted net loss per share	<u>\$ (0.86)</u>	<u>\$ (1.52)</u>	<u>\$ (0.40)</u>	<u>\$ (0.75)</u>
Weighted average number of shares used in computing basic and diluted net loss per share	<u>15,665,641</u>	<u>11,472,336</u>	<u>15,927,749</u>	<u>11,579,093</u>

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

INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of July 1, 2018	11,356,579	\$ (*)	\$ 244,204	\$ (215,697)	\$ 28,507
Stock-based compensation to employees, directors and non-employee consultants	151,916	(*)	2,196	-	2,196
Issuance of common stock under At Market Issuance Sales Agreement, net of issuance costs of \$148 (see Note 6a)	170,600	(*)	1,952	-	1,952
Exercise of options by employees and non-employee consultants	1,850	(*)	8	-	8
Net loss	-	-	-	(17,469)	(17,469)
Balance as of December 31, 2018 (unaudited)	11,680,945	\$ (*)	\$ 248,360	\$ (233,166)	\$ 15,194

(*) Less than \$1

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

INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of October 1, 2018	11,464,971	\$ (*)	\$ 246,012	\$ (224,483)	\$ 21,529
Stock-based compensation to employees, directors and non-employee consultants	82,374	(*)	869	-	869
Issuance of common stock under At Market Issuance Sales Agreement, net of issuance costs of \$121 (see Note 6a)	133,000	(*)	1,479	-	1,479
Exercise of options by employees and non-employee consultants	600	(*)	-	-	-
Net loss	-	-	-	(8,683)	(8,683)
Balance as of December 31, 2018 (unaudited)	11,680,945	\$ (*)	\$ 248,360	\$ (233,166)	\$ 15,194

(*) Less than \$1

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

INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of July 1, 2019	15,082,852	\$ (*)	\$ 272,825	\$ (251,004)	\$ 21,821
Stock-based compensation to employees, directors and non-employee consultants	201,155	(*)	1,631	-	1,631
Issuance of common stock under Open Market Sales Agreement, net of issuance costs of \$812 (see Note 6b)	1,644,118	(*)	5,967	-	5,967
Exercise of options by employees and non-employee consultants	5,000	(*)	-	-	-
Round up of shares due to reverse stock split effectuated on July 25, 2019 (see Note 1c)	1,292	(*)	-	-	-
Net loss	-	-	-	(13,509)	(13,509)
Balance as of December 31, 2019 (unaudited)	<u>16,934,417</u>	<u>\$ (*)</u>	<u>\$ 280,423</u>	<u>\$ (264,513)</u>	<u>\$ 15,910</u>

(*) Less than \$1

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

INTERIM CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of October 1, 2019	15,619,913	\$ (*)	\$ 275,670	\$ (258,143)	\$ 17,527
Stock-based compensation to employees, directors and non-employee consultants	108,286	(*)	767	-	767
Issuance of common stock under Open Market Sales Agreement, net of issuance costs of \$614 (see Note 6b)	1,204,218	(*)	3,986	-	3,986
Exercise of options by employees and non-employee consultants	2,000	(*)	-	-	-
Net loss	-	-	-	(6,370)	(6,370)
Balance as of December 31, 2019 (unaudited)	<u>16,934,417</u>	<u>\$ (*)</u>	<u>\$ 280,423</u>	<u>\$ (264,513)</u>	<u>\$ 15,910</u>

(*) Less than \$1

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Six months ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,509)	\$ (17,469)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	853	1,001
Stock-based compensation to employees, directors and non-employee consultants	1,631	2,196
Decrease (increase) in accounts receivable from the IIA	125	(24)
Increase in other current assets and other long-term assets	(719)	(1,245)
Decrease in trade payables	(378)	(1,041)
Decrease in other accounts payable, accrued expenses, other current liabilities and other long-term liabilities	(1,466)	(246)
Decrease in operating lease right-of-use asset and liability, net and effect of exchange rate differences	(103)	-
Decrease in interest receivable on short-term deposits	39	60
Linkage differences and interest on short and long-term deposits and restricted bank deposits	(7)	3
Accrued severance pay, net	(8)	(8)
Net cash used by operating activities	\$ (13,542)	\$ (16,773)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	\$ (128)	\$ (193)
Proceeds from short-term deposits	10,786	13,109
Repayment of (investment in) long-term deposits and restricted bank deposits	2	(6)
Net cash provided by investing activities	\$ 10,660	\$ 12,910

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. Dollars in thousands

	Six months ended December 31,	
	2019	2018
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds related to issuance of common stock, net of issuance costs	\$ 5,967	\$ 1,952
Exercise of warrants and options	-	8
Proceeds with respect to Israel-United States Binational Industrial Research and Development Foundation liability	-	107
Net cash provided by financing activities	\$ 5,967	\$ 2,067
Increase in cash and cash equivalents and restricted cash	3,085	(1,796)
Cash and cash equivalents and restricted cash at the beginning of the period	5,186	9,508
Cash and cash equivalents and restricted cash at the end of the period	\$ 8,271	\$ 7,712
(a) Supplemental disclosure of cash flow activities:		
Cash paid during the period for:		
Taxes paid due to non-deductible expenses	\$ 5	\$ 5
(b) Supplemental disclosure of non-cash activities:		
Purchase of property and equipment on credit	\$ 8	\$ 24

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:

	December 31,	
	2019	2018
	(Unaudited)	
Cash and cash equivalents	\$ 7,300	\$ 6,796
Restricted cash included in Restricted cash and short-term bank deposits	971	916
Cash, cash equivalents and restricted cash shown in the consolidated statement of cash flows	\$ 8,271	\$ 7,712

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

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

NOTE 1:- GENERAL

- a. Pluristem Therapeutics Inc., a Nevada corporation (“Pluristem Therapeutics”), was incorporated on May 11, 2001. Pluristem Therapeutics has a wholly owned subsidiary, Pluristem Ltd. (the “Subsidiary”), which is incorporated under the laws of the State of Israel. Pluristem Therapeutics and the Subsidiary are referred to as the “Company” or “Pluristem”. In January 2020, subsequent to the period end, the Subsidiary established a fully owned subsidiary, Pluristem GMBH (the “German Subsidiary”) which is incorporated under the laws of Germany.

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, inflammatory and hematologic conditions. The Company has incurred an accumulated deficit of approximately \$264,513 and incurred recurring operating losses and negative cash flows from operating activities since inception. As of December 31, 2019, the Company’s total stockholders’ equity amounted to \$15,910.

During the six-month period ended December 31, 2019, the Company incurred operating losses of \$13,563 and its negative cash flow from operating activities was \$13,542. 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, 2019, the Company’s cash position (cash and cash equivalents, short-term bank deposits and restricted cash and long-term bank deposits) totaled approximately \$17,060. 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 Israeli Innovation Authority (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, 2019, together with the funds received under the Open Market Sales AgreementSM (the “Sales Agreement”) with Jefferies LLC (“Jefferies”), as agent, during January 2020, will be sufficient to maintain the Company’s operations into the second quarter of the Company’s fiscal year 2021. 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 was a Phase II trial in Intermittent Claudication.

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.

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 entitled 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. As of December 31, 2019, commercial sale of the thawing device by Chart has not yet begun.

c. Reverse stock split

In July 2019, the Board of Directors approved a 1-for-10 reverse stock split of the Company's (a) authorized shares of common stock; (b) issued and outstanding shares of common stock and (c) authorized shares of preferred stock. The reverse stock split became effective on July 25, 2019. All shares of common stock, options, warrants and securities convertible or exercisable into shares of common stock, as well as loss per share, have been adjusted to give retroactive effect to this reverse stock split for all periods presented.

An additional 1,292 shares of common stock were included in the Company's issued and outstanding shares as a result of rounding fractional shares into whole shares as a result of the reverse stock split.

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).

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, 2019.

Operating results for the six month period ended December 31, 2019 are not necessarily indicative of the results that may be expected for the year ending June 30, 2020.

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.

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.

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).

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, 2019, the fair value of the options contracts was \$23, and is presented in "other current assets". The net income (expense) recognized in "Financial income (expense), net" during the three and six month periods ended December 31, 2019 and 2018 were (\$26), \$57 and (\$492), (\$405), respectively.

f. Recently Adopted Accounting Pronouncements

Accounting Standards Update ("ASU") No. 2016-02 - "Leases" ("Topic 842") and ASU No. 2018-11, "Targeted Improvements - Leases (Topic 842):

In February 2016 and July 2018, the Financial Accounting Standards Board ("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.

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 Company adopted the new standard as of July 1, 2019, using the modified retrospective approach. Consequently, prior period balances and disclosures have not been restated. The Company has elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard which does not require it to reassess the prior conclusions about lease identification, lease classification and initial direct costs. The adoption of Topic 842 resulted in the elimination of deferred participation payments of \$240 and \$381 in current and long-term liabilities in the Company's consolidated balance sheets, respectively.

Additionally, the Company included in its balance sheet, at adoption, operating right-of-use assets, short-term operating lease liabilities and long-term operating lease liabilities of \$1,631, \$964 and \$1,261, respectively. The standard had no material impact on the Company's net loss or its cash flows. For additional information regarding the Company's accounting for leases, please refer to Note 3.

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 adopted the new standard as of July 1, 2019, and the new standard had no material impact on its consolidated financial statements.

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 standard had no impact on the Company's consolidated financial statements.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**U.S. Dollars in thousands (except share and per share amounts)****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)***g. Recently Issued Accounting Pronouncements*

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, 2020 for the Company. The Company is currently evaluating the impact of adopting the ASU on its consolidated financial statements.

NOTE 3:- LEASES

The right-of-use asset and lease liability are initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate based on the information available at the date of adoption in determining the present value of the lease payments. The Company's incremental borrowing rate is estimated to approximate the interest rate on similar terms and payments and in economic environments where the leased asset is located.

The Company has various operating leases for office space and vehicles that expire through 2022. Below is a summary of our operating right-of-use assets and operating lease liabilities as of December 31, 2019:

	December 31, 2019 (Unaudited)
Operating right-of-use assets	\$ 1,484
Operating lease liabilities, current	(964)
Operating lease liabilities long-term	(1,039)
Total operating lease liabilities	\$ 2,003

The operating lease right-of-use assets are presented in long term assets net after elimination of deferred participation payments from Matam High-Tech and Business Park of \$240 and \$381 in current and long-term liabilities in the Company's consolidated balance sheets, respectively.

Minimum lease payments for our right of use assets over the remaining lease periods as of December 31, 2019 are as follows:

	December 31, 2019 (Unaudited)
2020	\$ 572
2021	1,092
2022	528
2023	1
Total undiscounted lease payments	\$ 2,193
Less: Interest	190
Present value of lease liabilities	\$ 2,003

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**U.S. Dollars in thousands (except share and per share amounts)****NOTE 3:- LEASES (CONT.)**

The components of lease expense and supplemental cash flow information related to leases for the six months ended December 31, 2019 were as follows:

	Six months ended December 31, 2019 (Unaudited)
Components of lease expense	
Operating lease cost	\$ 578
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	576
Sublease income	\$ 25

As of December 31, 2019, the weighted average remaining lease term is 2.1 years, and the weighted average discount rate is 10 percent. The discount rate was determined based on the estimated collateralized borrowing rate of the Company, adjusted to the specific lease term and location of each lease.

NOTE 4:- COMMITMENTS AND CONTINGENCIES

- a. As of December 31, 2019, an amount of \$971 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.

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

NOTE 4:- COMMITMENTS AND CONTINGENCIES (CONT.)

Through December 31, 2019, total grants obtained from the IIA aggregated to approximately \$27,685 and total royalties paid and accrued amounted to \$170. As of December 31, 2019, the Company's contingent liability in respect to royalties to the IIA amounted to \$27,515, not including LIBOR interest as described above.

- c. The Company was awarded a marketing grant under the "Smart Money" program of approximately \$112 from 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. 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, 2019, total grants obtained under this Smart Money program amounted to approximately \$112. As of December 31, 2019, the Company's contingent liability with respect to royalties for this "Smart Money" program was \$112 and no royalties were paid or accrued.

- d. 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, 2019, the aggregate amount of grant obtained from this Smart Money program was approximately \$102. As of December 31, 2019, the Company's contingent liability with respect to royalties for this "Smart Money" program is \$102 and no royalties were paid or accrued.

- e. In September 2017, the Company signed an agreement with the 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 ("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 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.

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

NOTE 4:- COMMITMENTS AND CONTINGENCIES (CONT.)

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, 2019, total grants obtained under the "Shalav" program amounted to approximately \$49. As of December 31, 2019, the Company's contingent liability with respect to royalties for this "Shalav" program was \$49 and no royalties were paid or accrued.

NOTE 5:- STOCKHOLDERS' EQUITY

- a. Pursuant to a shelf registration on Form S-3 declared effective by the Securities and Exchange Commission on June 23, 2017 (the "Form S-3"), 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 170,600 shares of common stock under the ATM Agreement at an average price of \$12.30 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.
- b. Pursuant to the Form S-3, on February 6, 2019 the Company entered into the Sales Agreement with Jefferies which provides that, upon the terms and subject to the conditions and limitations in the Sales 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 \$50,000 through Jefferies acting as sales agent. During the six month period ended December 31, 2019, the Company sold 1,644,118 shares of common stock under the Sales Agreement at an average price of \$4.12 per share for aggregate net proceeds of approximately \$5,967, net of issuance expenses of \$812.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**U.S. Dollars in thousands (except share and per share amounts)****NOTE 5:- STOCKHOLDERS' EQUITY (CONT.)**

c. Options to non-employees:

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, 2019 (Unaudited)			
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value Price
Options outstanding at beginning of period	89,580	\$ -	-	-
Options granted	-	-	-	-
Options exercised	(5,000)	-	-	-
Options forfeited	(4,125)	-	-	-
Options outstanding at end of the period	80,455	\$ -	7.57	\$ 317
Options exercisable at the end of the period	53,118	\$ -	8.15	\$ 209
Options vested and expected to vest	80,455	\$ -	7.57	\$ 317

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

	Six months ended December 31,		Three months ended December 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 33	\$ 97	\$ 15	\$ 13
General and administrative expenses	\$ 53	\$ 27	\$ 24	\$ 21
	\$ 86	\$ 124	\$ 39	\$ 34

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**U.S. Dollars in thousands (except share and per share amounts)****NOTE 5:- STOCKHOLDERS' EQUITY (CONT.)****d. Restricted stock ("RS") and restricted stock units ("RSUs") to employees, directors and consultants:****1. 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, 2019 (Unaudited):

	Number
Unvested at the beginning of period	795,633
Granted	18,000
Forfeited	(56,045)
Vested	(154,208)
Unvested at the end of the period	<u>603,380</u>
Expected to vest after December 31, 2019	<u>583,360</u>

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

	Six months ended December 31,		Three months ended December 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 414	\$ 440	\$ 192	\$ 121
General and administrative expenses	1,049	1,354	476	623
	<u>\$ 1,463</u>	<u>\$ 1,794</u>	<u>\$ 668</u>	<u>\$ 744</u>

Unamortized compensation expenses related to RSUs granted to employees and directors to be recognized over an average time of approximately 3.25 years are approximately \$2,425.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**U.S. Dollars in thousands (except share and per share amounts)****NOTE 5:- STOCKHOLDERS' EQUITY (CONT.)****d. RS and RSUs to employees, directors and consultants (cont.):****2. 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, 2019 (Unaudited):

	Number
Unvested at the beginning of period	30,107
Granted	33,000
Vested	(46,947)
Unvested at the end of the period	16,160

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

	Six months ended December 31,		Three months ended December 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Research and development expenses	\$ 23	\$ 18	\$ 11	\$ (8)
General and administrative expenses	59	260	49	98
	<u>\$ 82</u>	<u>\$ 278</u>	<u>\$ 60</u>	<u>\$ 90</u>

NOTE 6:- SUBSEQUENT EVENTS

From January 1, 2020 through February 6, 2020, the Company sold an aggregate of 925,480 shares of common stock at an average price of \$3.95 per share under the Sales Agreement.

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 terms, or 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;
- 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;
- our entering into certain contracts with third parties;
- 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, the Biomedical Advanced Research and Development Authority, or BARDA, as well as grants from other independent third parties;
- our marketing plans, including timing of marketing our product candidates, PLX-PAD and PLX-R18, and the filing of any requests for marketing authorization;
- 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 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;
- 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, 2019, or the 2019 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, muscle 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, South Korean 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 PLX cells in commercial quantities.

Our goal is to make significant progress with our clinical pipeline and our clinical 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 other territories 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 have determined to invest our resources primarily on the PLX-PAD Phase III clinical trials relating to CLI and muscle recovery following surgery for hip fracture, and focus on finalizing the clinical trials in the United States, Europe and Israel while we prepare for the marketing phase, with the initiation of such marketing phase subject to regulatory approval, in these territories.

Two Phase III multinational clinical trials are currently being conducted with our PLX-PAD product candidate: one in CLI, and the other in muscle recovery following surgery for hip fracture. In April 2019, we successfully enrolled over 50% of patients in our Phase III study in CLI, which allows for an interim analysis of efficacy after a one-year follow-up period under the European Medicines Agency's, or EMA, Adaptive Pathways pilot project, or the Adaptive Pathways Project, in which PLX-PAD was selected to participate. In December 2019, we successfully enrolled 75% of the patients and, 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 the European adaptive pathway, and in the first half of 2021 with respect to the United States. In December 2019, we successfully enrolled 50% of patients in our Phase III study in muscle recovery following surgery for hip fracture and, based on our current patient enrollment progress, we expect to complete the enrollment for our Phase III study in muscle recovery following surgery for hip fracture during the third quarter of 2020 and efficacy follow up by the end of the first quarter of 2021. We expect to release the clinical trial results shortly after the conclusion of the follow ups.

Our PLX-PAD cell program in CLI had been selected for the EMA's Adaptive Pathways Project, 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 \$8,500,000) 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 muscle recovery following surgery for hip fracture was also selected for the EMA's Adaptive Pathways Project and was awarded a Euro 7,400,000 (approximately \$8,300,000) 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 expected to advance to 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. We have submitted a proposal to BARDA to fund an additional non-human primates study, which is strategically designed to demonstrate the superiority of PLX-R18 versus current standards, with the goal of executing a full contract once the study is completed.

PLX-R18 is also under development in the United States and Israel for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation, or HCT. In March 2019, we announced that we had fully enrolled the second cohort of six patients in our ongoing Phase I clinical trial in HCT, and received data and safety monitoring board approval to continue to the final cohort of the trial. 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 HCT.

RESULTS OF OPERATIONS – THREE AND SIX MONTHS ENDED DECEMBER 31, 2019 COMPARED TO THREE AND SIX MONTHS ENDED DECEMBER 31, 2018.

Revenues

Revenues for both the six and three month periods ended December 31, 2019 were \$23,000, as compared to \$54,000 and \$50,000, respectively, in the six and three month periods ended December 31, 2018. All revenues 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 Horizon 2020 and IIA) for the six month period ended December 31, 2019 decreased by 23% from \$13,020,000 for the six month period ended December 31, 2018 to \$10,022,000. The decrease is mainly attributed to: (1) a decrease in materials consumption, (2) a decrease in subcontractor expenses related to a decrease in the initiation of sites for our clinical studies and other subcontractors related to materials productions, (3) a decrease in payroll expenses related to a decrease in the average number of employees, (4) a decrease in rent expenses due to the implementation of Accounting Standards Update No. 2016-02, "Leases," which resulted in a reduction of \$85,000 (for further information please refer to Note 3 in the accompanying financial statements to this Quarterly Report on Form 10-Q) and (5) a decrease in travel expenses related to our clinical studies. The decrease was partially offset by lower participation by the European Union with respect to the Horizon 2020 grants, due to the fact that most of the grant is utilized in the beginning of the projects.

Research and development expense, net (costs less participation and grants by the IIA and other parties) for the three month period ended December 31, 2019 decreased by 26% from \$6,256,000 for the three month period ended December 31, 2018 to \$4,640,000. The decrease is mainly attributed to: (1) a decrease in materials consumption, (2) a decrease in payroll expenses related to a decrease in the average number of employees and (3) a decrease in subcontractor expenses related to a decrease in the initiation of sites for our clinical studies and other subcontractors related to materials productions.

General and Administrative Expenses

General and administrative expenses for the six month period ended December 31, 2019 decreased by 18% from \$4,333,000 for the six month period ended December 31, 2018 to \$3,563,000. 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 payroll expenses related to a 25% reduction of the annual salary of our Chief Executive Officer, a 25% reduction of the annual compensation of our Executive Chairman and a decrease in the average number of employees.

General and administrative expenses for the three month period ended December 31, 2019 decreased by 17% from \$2,123,000 for the three month period ended December 31, 2018 to \$1,750,000. 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, a decrease in corporate activities expenses and a decrease in payroll expenses related to a 25% reduction of the annual salary of our Chief Executive Officer, a 25% reduction of the annual compensation of our Executive Chairman and a decrease in the average number of employees.

Financial Income (Expense), Net

Financial income (expense), net, increased from a net financial expense of \$168,000 for the six month period ended December 31, 2018 to a net financial income of \$54,000 for the six month period ended December 31, 2019. This increase is mainly attributable to changes in the fair value of our hedging instruments related to the strength of the U.S. dollar against the New Israel Shekel, or NIS, offset by the implementation of Accounting Standards Update No. 2016-02, "Leases," which resulted in an expense of \$180,000 (for further information please refer to Note 3 in the accompanying financial statements to this Quarterly Report on Form 10-Q) and expense from exchange rates related to the strength of the U.S. dollar against the NIS.

Financial expense, net, decreased from a net financial expense of \$352,000 for the three month period ended December 31, 2018 to a net financial expense of \$2,000 for the three month period ended December 31, 2019. 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 offset by the implementation of Accounting Standards Update No. 2016-02, "Leases," which resulted in an expense of \$78,000 (for further information please refer to Note 3 in the accompanying financial statements to this Quarterly Report on Form 10-Q) and expense from exchange rates related to the strength of the U.S. dollar against the NIS.

Net Loss

Net loss for the six and three month periods ended December 31, 2019 was \$13,509,000 and \$6,974,000, respectively, as compared to net loss of \$17,469,000 and \$8,683,000 for the six and three month periods ended December 31, 2018. The changes were mainly due to decreases in research and development expenses, as described above. Net loss per share for the six and three month periods ended December 31, 2019 was \$0.86 and \$0.40, respectively, as compared to \$1.52 and \$0.75 for the six and three month periods ended December 31, 2018.

For the six and three month periods ended December 31, 2019 and December 31, 2018, we had weighted average shares of common stock outstanding of 15,665,641, 15,927,749 and 11,472,336, 11,579,093, 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 April 2019, issuances of shares pursuant to our Open Market Sale AgreementSM, or the Sale Agreement, issuances of shares to employees and consultants, and shares issued as a result of exercises of options.

Liquidity and Capital Resources

As of December 31, 2019, our total current assets were \$19,227,000 and total current liabilities were \$6,991,000. On December 31, 2019, we had a working capital surplus of \$12,236,000, stockholders' equity of \$15,910,000 and an accumulated deficit of \$264,513,000. 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 non-dilutive sources.

Our cash and cash equivalents as of December 31, 2019 amounted to \$7,300,000 compared to \$6,796,000 as of December 31, 2018, and compared to \$4,106,000 as of June 30, 2019. Cash balances changed in the six months ended December 31, 2019 and 2018 for the reasons presented below.

Operating activities used cash of \$13,542,000 in the six months ended December 31, 2019, compared to \$16,773,000 in the six months ended December 31, 2018. Cash used in operating activities in the six months ended December 31, 2019 and 2018 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 \$10,660,000 in the six months ended December 31, 2019, compared to cash provided of \$12,910,000 for the six months ended December 31, 2018. The investing activities in the six month period ended December 31, 2019 consisted primarily of the withdrawal of \$10,786,000 of short term deposits, offset by payments of \$128,000 related to investment in property and equipment. 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.

Financing activities generated cash of \$5,967,000 during the six months ended December 31, 2019, compared to \$2,067,000 for the six months ended December 31, 2018. The cash generated in the six months ended December 31, 2019 from financing activities is related to net proceeds of \$5,967,000 from issuing shares of our common stock under our Sale Agreement. 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 (as defined below), 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.

In July 2017, we entered into the At Market Sales Agreement, or 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 could 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 were not obligated to make any sales of common stock under the ATM Agreement. From July 2017 through February 4, 2019, we sold an aggregate of 530,541 shares of common stock pursuant to the ATM Agreement at an average price of \$13.68 per share. On February 4, 2019, we notified the Agents of the termination of the ATM Agreement.

On February 6, 2019, we entered into 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. From February 6, 2019 through December 31, 2019, we sold an aggregate of 1,880,918 shares of common stock pursuant to the Sale Agreement at an average price of \$4.83 per share.

During the six months ended December 31, 2019, we received cash of approximately \$332,000 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, 2019, total grants obtained from the IIA aggregated to approximately \$27,685,000 and total royalties paid and accrued amounted to \$170,000.

The IIA has supported our activity in the past fourteen years. Our previous program, for the thirteen 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. Our most recent program, for the fourteenth year, was approved by the IIA in 2019 and relates to a grant of approximately \$500,000. The grant was used to cover research and development expenses for the period of January 1, 2019 to December 31, 2019.

As of December 31, 2019, we received total grants of approximately \$5,638,000 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 2019 Annual Report on form 10-K for the fiscal year ended June 30, 2019.

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, 2020, we have sold 3,900,000 shares of our common stock and warrants to purchase up to 2,857,143 shares of common stock in a total gross amount of \$36,051,000 in offerings we closed in October 2017 and April 2019, 530,541 shares of common stock in a total gross amount of \$7,258,542 pursuant to the ATM Agreement, 2,806,398 shares of common stock in a total gross amount of \$12,738,048 pursuant to the Sale Agreement, and may be deemed to have sold an additional \$37,261,952 pursuant to the Sale Agreement.

Outlook

We have accumulated a deficit of \$264,513,000 since our inception in May 2001. We do not expect to generate any significant revenues from sales of products in the next twelve months. Our cash needs may increase in the foreseeable future. We expect to generate revenues, from the sale of licenses to use our technology or products, but in the short and medium terms will unlikely exceed our costs of operations.

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, collaboration with other companies and sales of our common stock.

As of December 31, 2019, our cash position (cash and cash equivalents, short-term bank deposits and restricted cash and long-term bank deposits) totaled approximately \$17,060,000 and during January 2020, we raised approximately \$3,700,000 under the Sales Agreement. 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, 2019, together with the funds received under the Sales Agreement during January 2020, will be sufficient to maintain our operations into the second quarter of fiscal year 2021. 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 Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

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

Changes in Internal Control Over Financial Reporting - There has been no change in our internal control over financial reporting during the second quarter of fiscal year 2020 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, 2019, we issued an aggregate of 35,036 shares of common stock to a consultant for services rendered. In September 2019, we issued an aggregate of 1,000 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 6. Exhibits.

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

31.2* [Rule 13a-14\(a\) Certification of Chief Financial Officer.](#)

32.1** [Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.](#)

32.2** [Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.](#)

101 * The following materials from our Quarterly Report on Form 10-Q for the quarter ended December 31, 2019 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 Statements of Changes in Stockholders' Equity, (iv) 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/ Yaky Yanay

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

Date: February 6, 2020

By: /s/ Chen Franco-Yehuda

Chen Franco-Yehuda, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: February 6, 2020

CERTIFICATION

I, Yaky Yanay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluristem Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) of the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 6, 2020

/s/ Yaky Yanay

Yaky Yanay
Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATION

I, Chen Franco-Yehuda, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pluristem Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) of the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 6, 2020

/s/ Chen Franco-Yehuda
Chen Franco-Yehuda
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Quarterly Report (the "Report") of Pluristem Therapeutics Inc. (the "Company") on Form 10-Q for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, I, Yaky Yanay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 6, 2020

By: /s/ Yaky Yanay

Yaky Yanay

Chief Executive Officer and President

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Quarterly Report (the "Report") of Pluristem Therapeutics Inc. (the "Company") on Form 10-Q for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof, I, Chen Franco-Yehuda, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 6, 2020

By: /s/ Chen Franco-Yehuda

Chen Franco-Yehuda
Chief Financial Officer