UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **May 3, 2021 (May 3, 2021)**

PLURISTEM THERAPEUTICS INC.
(Exact Name of Registrant as Specified in Its Charter)

Nevada	**001-31392**	**98-0351734**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

MATAM Advanced Technology Park **Building No. 5** **Haifa, Israel**	**3508409**
(Address of Principal Executive Offices)	(Zip Code)

011 972 74 710 7171
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 per share	PSTI	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated into this Item 7.01 by reference, is an investor presentation of Pluristem Therapeutics Inc.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor presentation (furnished herewith)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PLURISTEM THERAPEUTICS INC.

By: */s/ Chen Franco-Yehuda*
Name: Chen Franco-Yehuda
Title: Chief Financial Officer

Date: May 3, 2021

Analyst and Investor Call - HCT Phase I Topline Results

May 3, 2021

Inspired by Life

Agenda

Yaky Yanay,
CEO and President

Hematological deficiencies
PLX-R18 product candidate
Company's pipeline

Nitsan Halevy, MD
Chief Medical Officer

Phase I HCT –
topline results

Jacob Rowe, MD, FACP
Director Hematology,
Shaare Zedek Medical Center,
Jerusalem

Clinical
perspective

Chen Franco-Yehuda,
CFO

Financial overview

Forward Looking Statements

This presentation contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss that PLX cells may provide a safer and more effective therapeutic benefit than current technologies, that PLX-R18 may potentially enhance the production of three blood cell lineages, that PLX-R18 may potentially reduce transfusion dependency, the belief that PLX-R18 affects the regeneration activity of the hematopoietic cells, its intention to push forward with the clinical development of PLX-R18 with the goal of establishing it as the new standard of care in the field and the expected timing of the expected end of enrollment in our various studies. These forward-looking statements and their implications are based on the current expectations of our management only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting us, reference is made to our reports filed from time to time with the Securities and Exchange Commission.

Hematological Deficiencies

Phase I

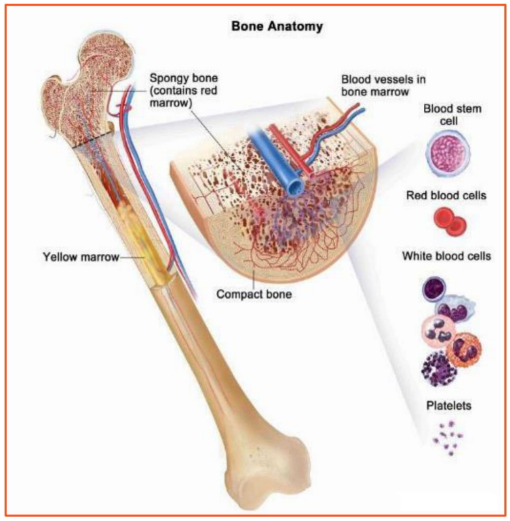
Open-label, dose-escalation study to evaluate the safety of intramuscular injections of PLX-18 in subjects with incomplete hematopoietic recovery following Hematopoietic Cell Transplantation **(HCT)**

The Need: Poor Graft Functions

- In patients suffering from a life-threatening condition of incomplete hematopoietic recovery, graft function remain poor, in which they fail to develop satisfactory blood counts in some or all blood cell lineages

- **Available current treatments target only one of the three blood cell lineages**

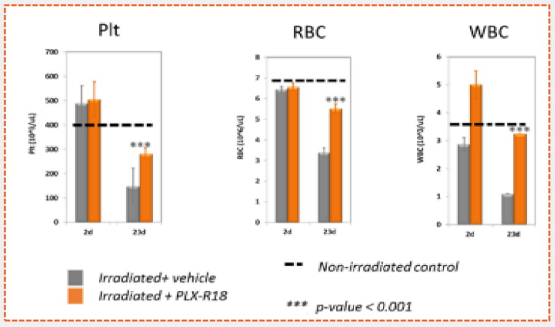
- These patients are vulnerable to bleeding and recurrent infections, requiring repeated costly transfusions of blood products, which only provide a short-term solution



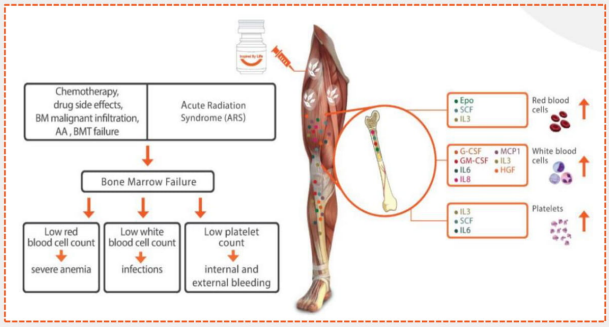
PLX-R18: Hematological Deficiencies

PLX-R18 is designed to stimulate the regeneration of damaged bone marrow to **produce all blood cell lineages – white, red and platelets**

Preclinical studies: Significant recovery of the three blood cell types (p<0.001)



PLX-R18: Mechanism of Action (MoA)



PLX-R18

Manufactured in **3D** cell expansion system, in **our GMP certified cell manufacturing facility**

PLX-R18 is the first product candidate that Pluristem manufactures using our developed **serum-free media**

PLX Platform

Clinical pipeline

PLX-PAD

- Phase III – Muscle regeneration following Hip Fracture
- Phase II – ARDS complicated by COVID-19
- Phase I/II cGvHD

PLX-R18

- Phase I – HCT
- Animal Rule – ARS (Acute Radiation Syndrome)

Developments

PLX Immune

Induced with tumor necrosis factor alpha (TNF-a) and interferon-gamma (IFN-g)

Next generation

Genome-Editing Solutions for PLX Cells

Clinical Pipeline

PRODUCT	FOCUS	INDICATION	LOCATION	FUNDING/ PARTNER	PHASE I / PHASE II / PHASE III	STATUS
PLX-PAD	Muscle Injuries	Muscle Regeneration following Hip Fracture	U.S., Europe, Israel			Over 85% enrolled Expected end of enrollment in the coming quarter
	Inflammatory Diseases	ARDS associated with COVID-19	U.S., Europe, Israel			Expected end of enrollment Europe, Israel – H1\2021 U.S. – H2\2021
		Chronic Graft vs Host Disease (cGvHD)	Israel			Investigator study – enrolling for cohort II
PLX-R18	Hematological Deficiencies	Acute Radiation Syndrome (ARS)*	U.S.	NIH NIAID		Next Phase – subject to governmental funding
		Hematopoietic Recovery Following Hematopoietic Cell Transplantation (HCT)	U.S., Israel			Completed enrollment

*Via FDA Animal Rule

Robust preclinical data in variety of indications

PLX-R18 as a Treatment for Hematological Deficiencies

A Phase I study (n= 21 patients) of patients with persistent deficiency of at least one blood cell types (platelets, hemoglobin and neutrophil counts) suffering from poor graft function following HCT.

- PLX-R18 was **well-tolerated with a favorable safety profile**
- At 6-months, follow up of patients treated with PLX-R18 had:
  - Significant **improvement in all 3 blood cell types: platelets, hemoglobin and neutrophil counts**
  - Substantial **reduction in transfusion dependency**

PLX-R18-HCT-01: Open-label, Dose-Escalation, Phase I Study (NCT03002519)

Study population:
Incomplete hematopoietic recovery persisting > 3 months after HCT

Inclusion Criteria:
PLT ≤50,000/µL and/or
Hb ≤8g/dL and/or
ANC ≤1,000/µL

Sample Size:
21 patients

Countries:
USA & Israel

Cohort 1
$1x10^6$ /kg
n=3

Cohort 2
$2x10^6$ /kg
n=6

Cohort 3
$4x10^6$ /kg
n=12

Study Endpoints:
1. Safety
2. Exploratory
Changes in platelet, hemoglobin and neutrophil concentrations, transfusion dependency

Follow up:
12 months

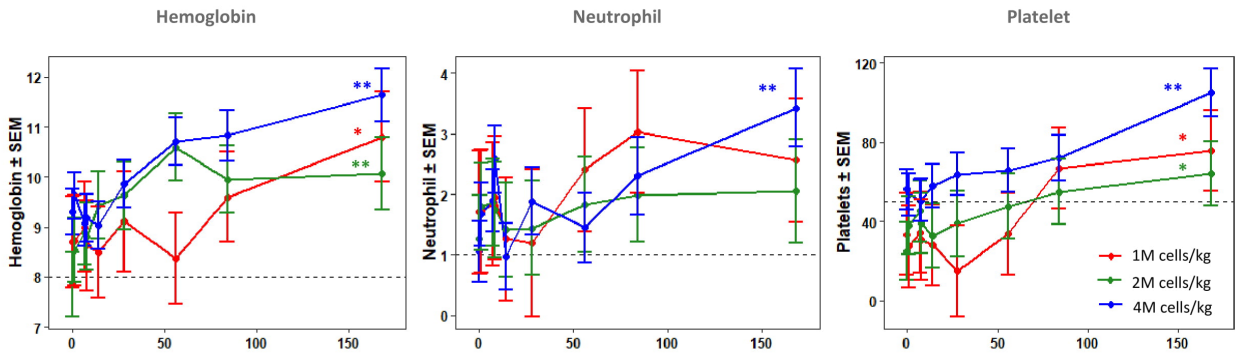
Analysis up to 6-months will be presented

14 patients reached 6-month follow-up

Patients Clinical Characteristics (n=21)

Variables	Value
Median Days From HCT to Treatment (range)	236 (118-872)
Mean Patients Age (range)	56 (29-75)
Gender, male (%)	12(57%)
HCT Type, allogeneic (%)	19 (90%)
Disease Types	
Acute Lymphoblastic Leukemia	7 (33%)
Acute Myelogenous Leukemia	3 (14%)
Burkitt Lymphoma	1 (5%)
Multiple Myeloma	2 (10%)
Myelodysplastic Syndrome	2 (10%)
Myelofibrosis	3 (14%)
Nodular Sclerosing Hodgkin lymphoma	1 (5%)
Non-Hodgkin's Lymphoma	2 (10%)

Improvement in All Three Blood Cell Lineages

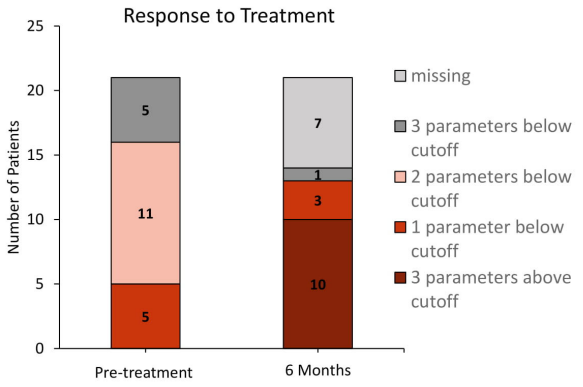


- * <0.05, ** <0.01
- SEM, standard error mean
- Mixed Model Repeated Measure (MMRM)
- Dotted horizontal line in each plot is cutoff for inclusion

Response to Treatment

At 6-month follow-up, 10 patients that were treated with PLX-R18 showed response in all 3 blood cell types

Response defined as:
Platelet ≥ 50,000/µL and
Hemoglobin ≥ 8 g/dL and
Neutrophil ≥ 1000/µL



Substantial Reduction in Transfusion Dependence at 6-Months

At 6-months, 46% of the patients treated with PLX-R18 become transfusion independent

Jacob M. Rowe, MD, FACP - Disclosures

- Member of Pluristem HCT clinical study advisory board
- Consultant - BioSight

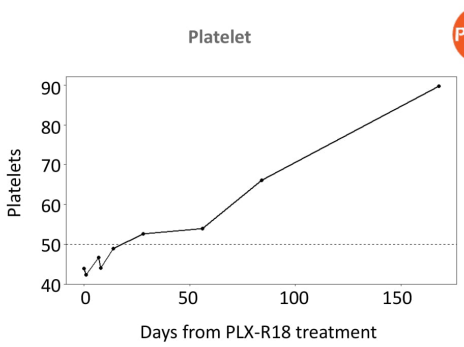
Jacob M. Rowe, MD, FACP

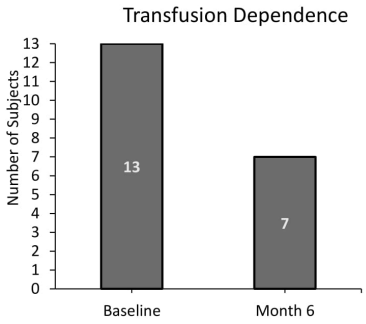
Current position:

- Shaare Zedek Medical Center in Jerusalem, Hematology
- Ann and Pinky Sohn Chair in Hemato-Oncology
- Editor-in-Chief, Haematologica

Former positions:

- University of Rochester Medical Center
  - Director of Clinical Services , Hematology
  - Founding Director of the Bone Marrow Transplant Program
- Technion, Rappaport Faculty of Medicine, Israel
  - Associate Dean for Clinical Affairs
  - Dresner Chair in Hemato-Oncology
- Rambam Medical Center
  - Director, Hematology and Bone Marrow Transplantation
  - Associate Editor, BLOOD





What is Next

- One year follow up
- We intend to proceed the clinical development of PLX-R18 with the goal of establishing it as the new standard of care in the field

Financials

Cash: ~$74 million
(as of March 31, 2021)

EIB non-dilutive financing agreement: First tranche of €20M expected during H1 of 2021 calendar year*

European Investment Bank The EU bank

* https://www.sec.gov/Archives/edgar/data/1158780/000121390020026105/f10k2020ex10-20_pluristem.htm#a_016

Thank you

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