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): **April 30, 2020 (April 30, 2020)**

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 Capital 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 1.01 Entry into a Material Definitive Agreement.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

On April 30, 2020, Pluristem Therapeutics Inc., or the Company, Pluristem Ltd., the Company's Israeli subsidiary, and Pluristem GmBH, the Company's German subsidiary, or the Borrower, entered into a Finance Contract, or the Finance Contract, with the European Investment Bank, or the Bank, pursuant to which the Borrower obtained a loan in the amount of €50 million, or the Loan, payable in tranches, subject to the achievement of certain clinical, regulatory and scale up milestones. Each of the Company and Pluristem Ltd. are guarantors under the Finance Contract.

Pursuant to the terms of the Finance Contract, the Borrower is required to use the funds provided by the Loan for the development of (i) PLX-PAD for the treatment of critical limb ischemia, or CLI, muscle regeneration following hip fracture, intermittent claudication and chronic graft-versus-host-disease; (ii) PLX-R18 for the treatment of acute radiation syndrome and incomplete hematopoietic recovery following hematopoietic cell transplantation; and (iii) PLX cells being tested under compassionate use programs or any other clinical program for complications caused by COVID-19, or collectively the Investment. The Finance Contract provides that the Loan amount will not exceed 50% of the cost of the Investment and further provides that a maximum of €10 million may be used for therapies targeting COVID-19, unless a successful compassionate study completed in any European county indicates positive results.

The Loan is not secured and will be disbursed in three tranches consisting of one tranche of €20 million, or the First Tranche, a second tranche of €18 million, or the Second Tranche, and a third tranche of €12 million, or the Third Tranche, each as may be requested by the Borrower, subject to the achievement of clinical, regulatory and scale up milestones.

In conjunction with the Finance Contract, the Borrower also agreed to pay the Bank a penalty of 1% of the Loan in the event no disbursement of the Loan is made within 6 months of the execution of the Finance Contract, unless the Company has not achieved the milestones that allow the disbursement.

The Tranches will be treated independently, each with its own interest rate and maturity period. The fixed interest rate is 0% per annum for the First Tranche and 1.00% for each of the Second Tranche and Third Tranche. The deferred interest rate is 4% per annum for the First Tranche, 3% for the Second Tranche and 2% for the Third Tranche.

The Borrower is required to repay the First Tranche and the Second Tranche, with all other amounts owed thereunder, in a single installment on the maturity date of that tranche, following the five-year anniversaries from each of the First Tranche and the Second Tranche disbursements. The Borrower is required to repay the Third Tranche, with all other amounts owed thereunder, in two equal installments, with the first such payment following the fourth anniversary of the disbursement date and the last repayment on a date not later than five years from the disbursement date. In addition, any early prepayment of the Loan is subject to certain prepayment penalties as specified in the Finance Contract.

In addition to any interest payable on the Loan, the Bank is also entitled to royalty payments, pro-rated to the amount disbursed from the Loan, on the Company's consolidated revenues beginning in the fiscal year 2024 up to and including its fiscal year 2030, in an amount equal to up to 2.3% of the Company's consolidated revenues below $350 million, 1.2% of the Company's consolidated revenues between $350 million and $500 million and 0.2% of the Company's consolidated revenues exceeding $500 million.

Item 7.01. Regulation FD Disclosure.

On April 30, 2020, the Company held an Investor & Analyst Call pursuant to which it shared a presentation relating to the Bank Loan. The presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On April 30, 2020, the Company held an Investor & Analyst Call pursuant to which the Company updated participants that, as of April 30, 2020, it has cash and deposits of approximately $44 million, and assuming the full receipt of the Loan, such amount is expected to total $100 million as compared to approximately $17 million on December 31, 2019, and is expected to fund the Company's operations for the next 3 years.

In addition, the Company updated that it has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration, or FDA, and a Clinical Trial Authorization application has been submitted in Europe, starting with Germany and Italy. The Company further updated that it intends to commence Phase II studies of PLX cell therapy in the treatment of complications arising from COVID-19 as soon as it receives clearance from regulators in the U.S. and Europe. Anticipating responses in the next few weeks, the Company's goal is to complete enrollment and treatment in a few months, by utilizing its logistical and technological competitive advantages to support effective enrollment. In parallel, the Company plans to conduct an Expanded Access Program in both the U.S. and Europe. The Company believes the clinical development of this indication will be expedited as a result of the Loan.

The Company also provided updates on the critical limb ischemia, or CLI, Phase III study and its Phase III study on muscle regeneration following hip fracture. With respect to the CLI Phase III study, the Company advised that it is advancing with more than 80% patients enrolled, that enrollment has slowed in April, 2020, and that the Company is now finalizing discussions with the FDA and European Medicines Agency regarding the data readout, confirming understandings on endpoint, timing, and procedures for cleaning data during COVID-19 limitations. The Company expects the announcement of the interim readout top line results to be delayed to the beginning of the fourth quarter of calendar year 2020. The Company is and will continue to closely follow the guidelines that will enable access to the clinical sites to clean the data prior to data lock. With respect to the Phase III study on muscle regeneration following hip fracture, the Company advised that the study is more than 60% enrolled, and that enrollment has slowed in April, 2020. The Company advised that it has been working to secure Short Physical Performance Battery (SPPB) data capture, working with the sites on home monitoring. The Company intends to provide guidelines for expected end of enrollment for both studies once it has greater clarity of the impact of COVID-19 on the enrollment rates in each respective study.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Investor & Analyst Call Financing Agreement between Pluristem and EIB, dated April 30, 2020

Warning Concerning Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, the Company is using forward-looking statements when it discuss the intended use of proceeds of the Loan from the Bank to support its research and development to further advance its regenerative cell therapy product candidates, with a special focus on the treatment of complications associated with COVID-19, the belief that its financial resources are expected to fund its operations for the next three years, the expected timing of interim data readouts, patient enrollments and the timing of public announcements of its clinical trials, and the timing of enrollment of certain studies, and the expected response from regulators, with respect to its IND application for the use of its PLX cells for the treatment of complications associated with COVID-19. These forward-looking statements and their implications are based on the current expectations of the management of the registrant 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies; Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; 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; Pluristem's patents may not be sufficient; Pluristem products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications and; loss of market share and pressure on pricing resulting from competition, which could cause Pluristem's actual results or performance to differ materially from those contemplated in such forward-looking statements. In addition, historic results of scientific research do not guarantee that the conclusions of future research would not suggest different conclusions or that historic results would not be interpreted differently in light of additional research or otherwise. Except as otherwise required by law, the Company undertakes 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 the registrant, reference is made to the Company's reports filed from time to time with the Securities and Exchange Commission.

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.

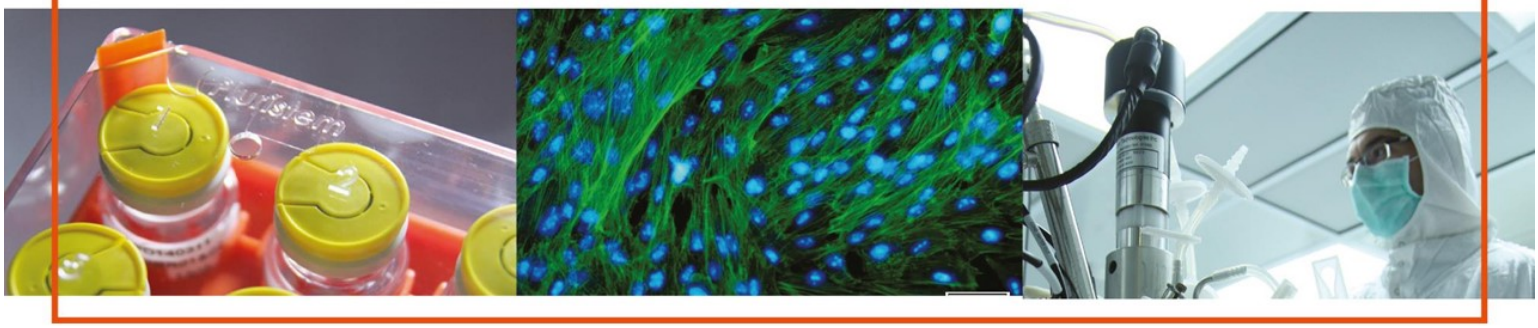
By: */s/ Chen Franco-Yehuda*
Name: Chen Franco-Yehuda
Title: Chief Financial Officer

Date: April 30, 2020

Exhibit 99.1

Financing Agreement between Pluristem and The European Investment Bank (EIB)

Investor & Analyst call, April 30, 2020



Pluristem Therapeutics Inc.

kENUP foundation

European Investment Bank The EU bank

Forward looking Statements

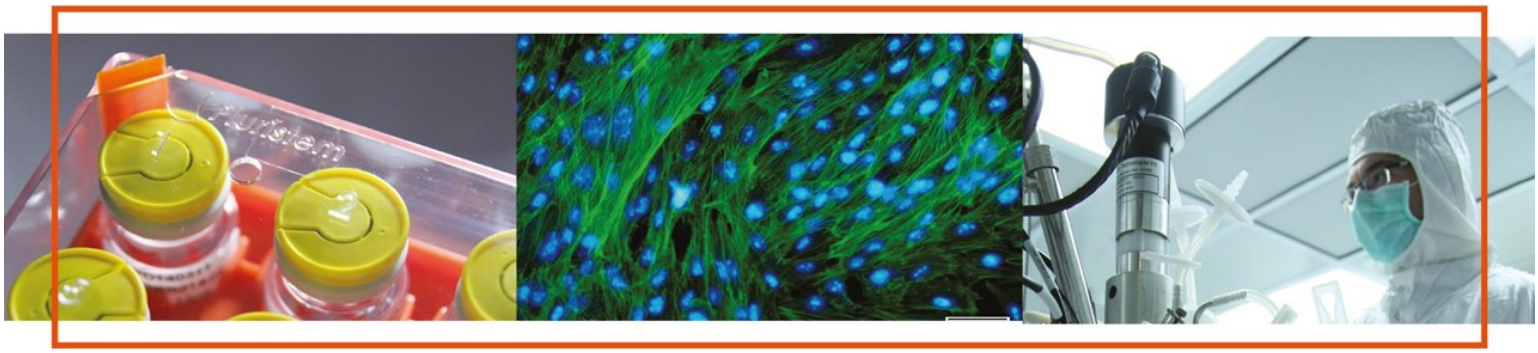
This presentation contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss the intended use of proceeds of the loan from the European Investment Bank (the "EIB") to support our research and development in the EU to further advance our regenerative cell therapy product candidates, with a special focus on the treatment of complications associated with COVID-19, the belief that our financial resources are expected to fund our operations for the next three years, the expected timing of interim data readouts, patient enrollments and the timing of public announcements of our clinical trials, and the timing of enrollment of certain studies, and the expected response from regulators, with respect to our investigational new drug application for the use of our PLX cells for the treatment of complications associated with COVID-19. 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.

AGENDA

- **Opening** (Yaky Yanay, CEO and President)
- **kENUP foundation** (Holm Keller, Chairman)
- **European Investment Bank** (Anna Stodolkiewicz, Investment Officer)
- **Pluristem Financing Agreement** (Chen Franco-Yehuda, Chief Financial Officer)
- **Pluristem CEO Update on Clinical Pipeline and COVID-19 Project** (Yaky Yanay, CEO and President)
- **Q&A Session**

Investor & Analyst call

Yaky Yanay, CEO & President



Pluristem Therapeutics Inc.

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European Investment Bank The EU bank

Executive Summary – Pluristem

Platform technology

- Placenta derived cells – unlimited source
- Demonstrated in clinical studies the ability to treat broad range of diseases conditions including ischemia associated with diabetes complications, muscle regeneration, blood cell restoration, controlling inflammation, immunomodulation
- Demonstrated favorable safety profile in clinical studies – hundreds of patients treated worldwide without significant adverse events

Late stage development company

- Two phase III studies and broad pipeline of additional earlier phase II studies addressing significant unmet medical needs
- Targeting multi billion dollar indications*
- Indications selected based on combination of patient need, market size and likelihood of therapeutic benefit using our cells

* based on internal research

Executive Summary – Pluristem

Industrialized commercial scale manufacturing established

- State-of-the-art manufacturing using proprietary 3D cell manufacturing system
- Existing facility capable of manufacturing commercial scale for several product launches with competitive cost of goods
- Necessary regulatory approvals in place with the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Israel
- Scalable technology for additional commercial capacity

Biopharmaceutical off-the-shelf product

- Therapeutic effect is accomplished by the release cocktail of cytokines (proteins), the cells are pre-conditioned by our culture conditions for a particular disease
- No special preparation is required to administer our cells
- Our cells do not require administration of any immunosuppressive drugs – they do not engraft and do not differentiate into other cell types; rather, they deliver the therapeutic proteins that have the long term regenerative effect

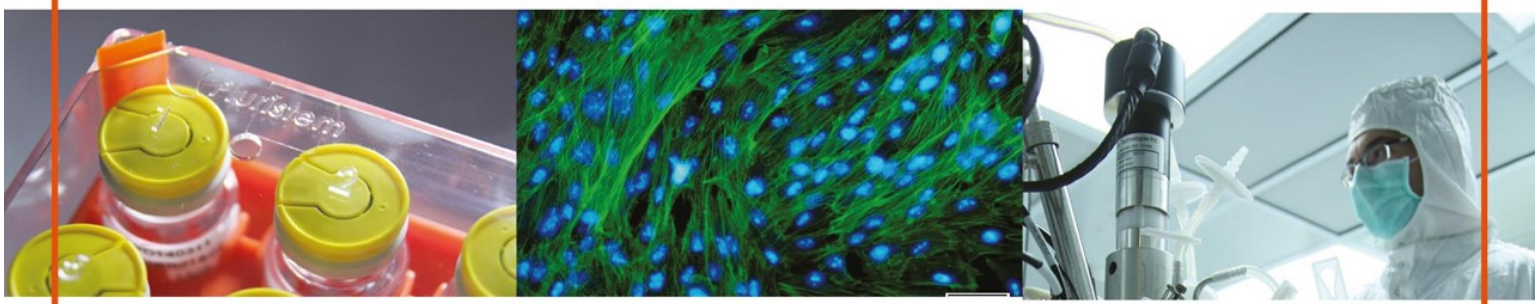
Executive Summary – Pluristem

Significant investment made to date developing and maturing advanced assets

- Our clinical platform
- Our manufacturing platform
- Network of partners, supported by the Israel Innovation Authority, Horizon 2020 in collaboration w/Charité as a development partner, U.S. (National Institutes of Health/ National Institute of Allergy and Infectious Diseases/ Department of Defense) and now with the EIB
- Approximately 140 patents granted/allowed covering our 3D culture technology, compositions of matter, methods of treatment and devices and additional technologies

Investor & Analyst call

Holm Keller, kENUP Chairman



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kENUP Overview *Promoting Innovation in Europe*

kENUP foundation

Investment Platforms

covidX
EU Malaria Fund
Bio-Convergence Co-Investment Scheme
Vaccines for Europe

alongside
individual projects through non-dilutive venture debt from public promotional banks in the European Union

Financial Data

Investment procured €300m (2020, expected)
Overhead share < 0.2% of capital engaged in

Working in association with

European Investment Bank (EIB)
Investitionsbank Berlin (IBB)
Malta Development Bank (MDB)
Cassa Depositi e Prestiiti SpA (CDP)
Israel Innovation Authority

Republic of Malta
Republic of Slovenia
Republic of Croatia
Federal State of Berlin

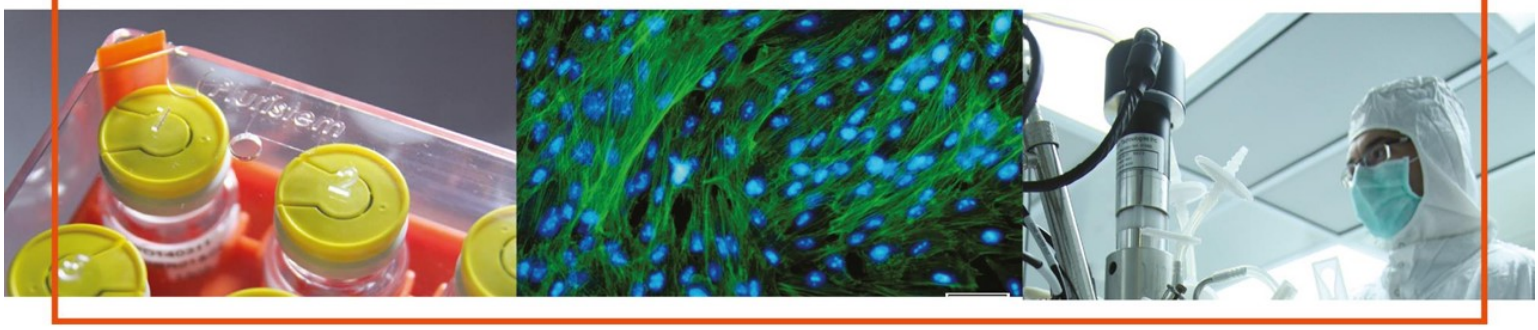
World Health Organization (WHO)
Organization for Economic Co-operation and Development (OECD)
G20 Health and Development Partnership
National Academy of Medicine (NAM, former IOM)

Organization

Public Benefit Foundation, established 2014 by Public Deed in the Republic of Malta
Governed by a Board of Directors
Listed in the European Transparency Register
Fully owned subsidiary kENUP Limited acting as investment vehicle
Eight core staff, supported by substantive, professional volunteer base
Two locations: kENUP Building at Chaplain's House, Kalkara, Malta; rented offices Berlin, Germany

Investor & Analyst call

Anna Stodolkiewicz, EIB, Investment Officer



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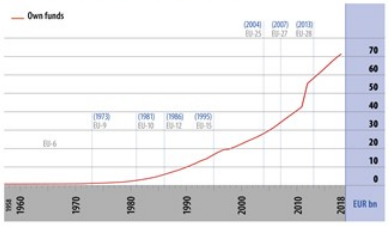
EIB at a Glance

EIB own resources since 1958



- Established in 1958, with the Treaty of Rome
- Shareholders: 27 Member States of the EU
- Invests in projects supporting EU policy:
  - Environment, Innovation, Small Businesses, Infrastructure
  - 90% of lending in EU, 10% abroad
- Parent of the European Investment Fund (EIF)
- AAA-rated bonds by all major rating agencies
- EIB Group figures (2019):
  - Total financing: 72 billion Euro
  - Number of operations signed: 1095

Quasi Equity / Venture debt - Target Companies

- **Innovative company** with growth driven by the value of your own intellectual property, and no access to bank debt
- Start-up, small and medium-sized enterprises, with **less than 3,000 employees** and growing, including pre-profit companies
- Company already **raised Series B/C** venture equity and needs additional financing to accelerate growth
- Strong and sustainable **business** model/plan, professional **management** & investors, and established corporate **governance**
- Investments to be financed are **located in the EU**, amounting to **at least 2x the size of the requested financing**

Advantages for Stakeholders

Companies

- Increase runway to next milestone or funding round
- Extend runway to cash positive
- Provide cushion

Founders

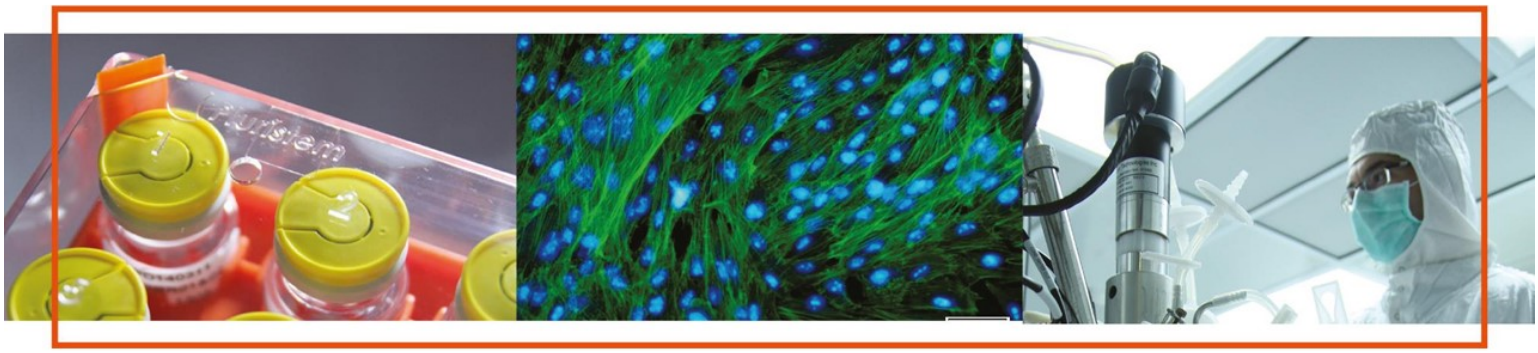
- Limited dilution & loss of control
- Extend time between next funding round
- Hands-off approach with no direct involvement

Investors

- Complementary to existing equity investment
- Return enhancement
- Maintenance of control
- Long-term loans match timing of investment

Investor & Analyst call

Chen Franco-Yehuda, Pluristem, CFO



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Finance Agreement Highlights

- **Total financing** – 50 Million Euro
- **Availability period** – 36 months from signing (by April 30, 2023)
- **Purpose** –
  To support Pluristem's research and development in the EU to further advance its regenerative cell therapy platform, and to assist moving the product candidates in its pipeline to market, with a special focus on clinical development of placenta expanded (PLX) cells as a treatment for complications associated with COVID-19. Such financing will not exceed 50% of the total cost of the project
- **Non Secured Loan**
- **Tranches** -
  Each tranche will be disbursed following the achievement of certain clinical, regulatory and scale up milestones. The tranches are divided as follows:
  - A – 20 Million Euro
  - B – 18 Million Euro
  - C – 12 Million Euro

Finance Agreement Highlights

- **Maturity – Each tranche will be treated independently from the others, with the following repayment dates:**
  - A – 20 Million Euro, will be repaid 5 years following its disbursement
  - B – 18 Million Euro, will be repaid 5 years following its disbursement
  - C – 12 Million Euro, will be repaid in 2 annual installments starting the 4th anniversary from its disbursement
- **Interest –**
  - A – 4% deferred annual interest, paid at maturity of the tranche
  - B – 3% deferred annual interest, paid at maturity of the tranche, and 1% annual cash interest
  - C – 2% deferred annual interest, paid at maturity of the tranche, and 1% annual cash interest
- **Royalties – to be paid on Pluristem's revenues, between fiscal years 2024-2030, pro-rated to the amount disbursed from the full financing, as follows:**
  - 2.3% of Pluristem's annual revenue on consolidated basis applying on the portion of less than 350 Million USD
  - 1.2% of Pluristem's annual revenue on consolidated basis applying on the portion between 350 Million USD and 500 Million USD
  - 0.2% of Pluristem's annual revenue on consolidated basis exceeding 500 Million USD

  Pluristem can buy back the royalty commitment, such payment will not exceed 50 Million Euro

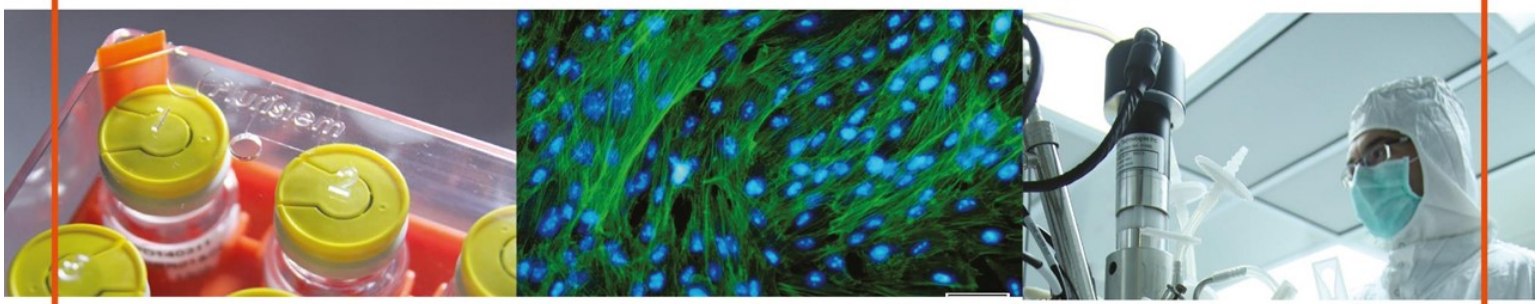
Finance Highlights

- **Cash & deposits on April 30, 2020 ~ $44 Million***
- At-The-Market (ATM) facility
- Exercise of warrants
- Grants obtained from approved Horizon 2020 program
- We believe thar our current available resources, including the funds from the EIB financing, together approximately $100 Million, expected to fund the operations of the company for the coming 3 years

*Since Jan. 1, 2020

Investor & Analyst call

Yaky Yanay, Pluristem, CEO & President



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CEO Update on Clinical Pipeline and COVID-19 Project

- **Our rules:**
  - Patient's safety and medical team safety come first
  - Currently following the "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic", issued on March 18, 2020, and the EMA "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic" issued on March 20, 2020

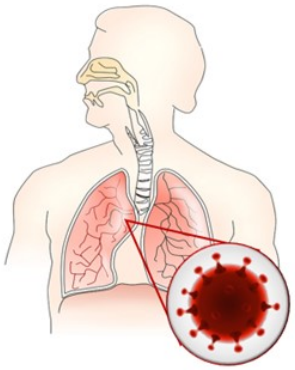
Clinical Pipeline Update

- **Critical Limb Ischemia (CLI) project status:**
  - More than 80% enrolled, we have slowed down enrollment in April 2020
  - Finalizing discussions with FDA/EMA towards readout, confirming understandings, including endpoint, timing and procedures of cleaning data during COVID-19 limitations
  - Interim readout: we expect the top line results announcement to be delayed to the beginning of the fourth quarter of calendar year 2020, as we closely follow the guidelines that will enable access to our clinical sites to clean the data prior to data lock
  - We will provide guidelines for expected end of enrollment of the entire study once we have better clarity of the impact of the COVID-19 on the enrollment rate
- **Muscle Regeneration following Hip Fracture Surgery (HIP) project status:**
  - More than 60% enrolled, we have slowed down enrollment in April 2020
  - We work hard to secure Short Physical Performance Battery (SPPB) data capture, working with the sites on home monitoring
  - We will provide guidelines for expected end of enrollment of the entire study once we have better clarity of the impact of the COVID-19 on the enrollment rate

COVID-19 Project

- Approximately 14% of COVID-19 patients develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit*
- In severe cases, COVID-19 can be complicated by the acute respiratory distress syndrome (ARDS), sepsis and septic shock, multi-organ failure, including acute kidney injury and cardiac injury, which are associated with high risk for mortality rate**

- Our product candidate PLX-PAD has anti-inflammatory and immunomodulatory properties, potentially leading to reduction of inflammation and lung injury
- Safety profile observed from clinical trials involving hundreds of patients worldwide
- Reported follow up on seven patients in Israel under compassionate use program and initiating Single Patient Expanded Access Program in the U.S.



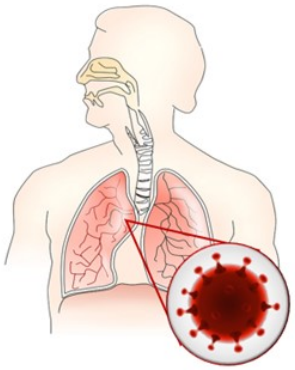
* Source: World Health Organization

** Pavan K. Bhatraju et al. https://www.nejm.org/doi/full/10.1056/NEJMoa2004500 , Safiya Richardson et al. https://jamanetwork.com/journals/jama/fullarticle/2765184

COVID-19 Project- What's Next?

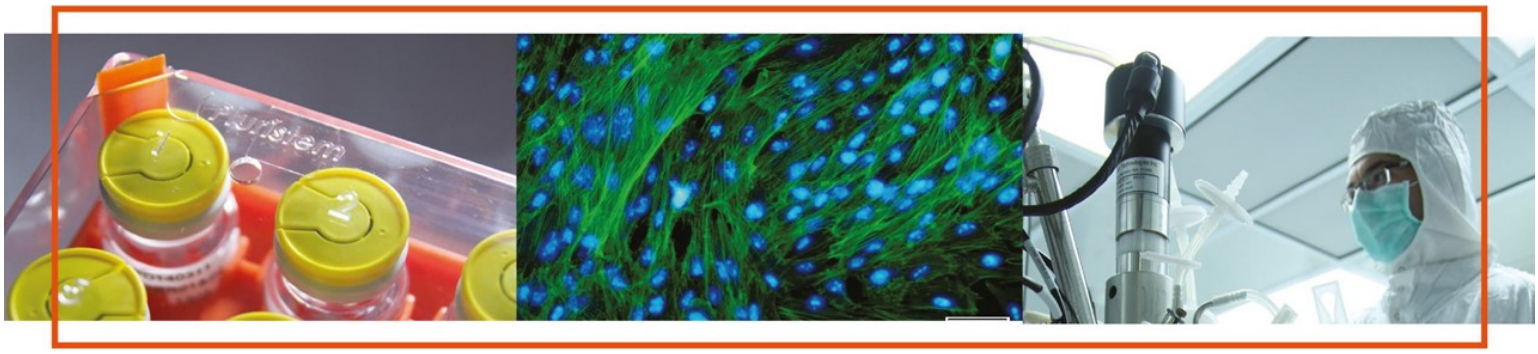
- We have filed an Investigational New Drug (IND) application and Clinical Trial Application (CTA) in Europe (starting Germany and Italy) for Phase II studies, expecting answers in the next couple of weeks
- Initiation of studies
- Our goal: complete enrollment within few months - we hope to utilize our logistic and technological competitive advantage to support effective enrollment
- Parallel Expanded access program in both territories
- We expect that the EIB funding will allow us to expedite the process

European Investment Bank



Pluristem

Q&A Session



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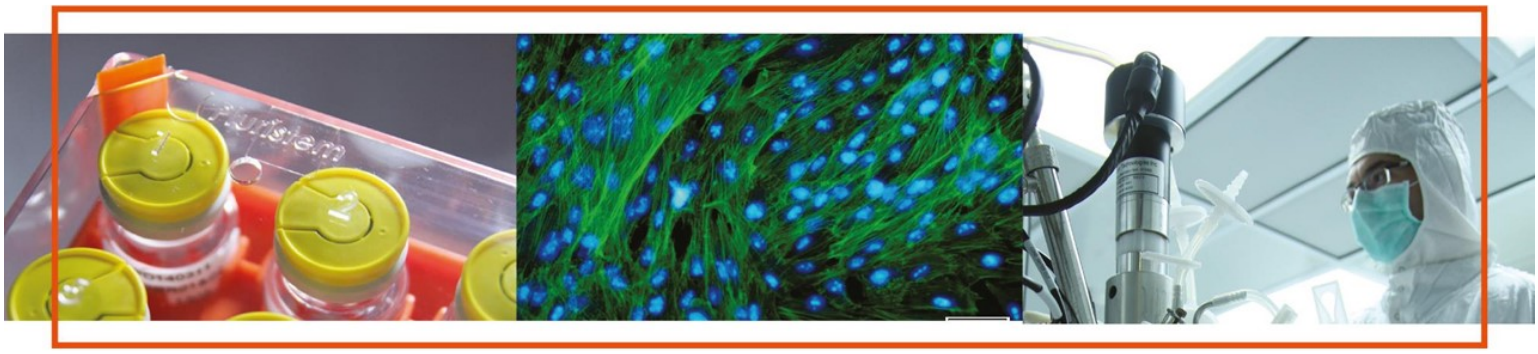
Thank you



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