

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 7, 2020 (April 7, 2020)**

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

**Nevada**  
(State or Other Jurisdiction  
of Incorporation)

**001-31392**  
(Commission File Number)

**98-0351734**  
(IRS Employer  
Identification No.)

**MATAM Advanced Technology Park  
Building No. 5  
Haifa, Israel**

(Address of Principal Executive Offices)

**3508409**  
(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 8.01. Other Information.**

On April 7, 2020, Pluristem Therapeutics Inc. issued a press release reporting preliminary data from its COVID-19 compassionate use program in Israel after treating seven patients suffering from acute respiratory failure. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release dated April 7, 2020</a>

## 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 7, 2020



## **Pluristem Reports Preliminary Data from its COVID-19 Compassionate Use Program, Treating Seven Patients with Acute Respiratory Failure**

- All treated patients were in Intensive Care Units (ICU) on ventilators and suffered from Acute Respiratory Distress Syndrome (ARDS)
- 100% survival rate for all seven patients
- 6 patients completed 1 week follow up; the seventh patient was treated on April 5 2020
- 4 of the 6 (66%) patients that completed 1 week follow up demonstrated improvement in respiratory parameters
- 3 of the 6 (50%) patients that completed 1 week follow up are in advanced stages of weaning from ventilators
- Pluristem plans to apply for initiation of multinational clinical trial for treatment of complications associated with COVID-19

**HAIFA, Israel, April 7, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today preliminary data from its compassionate use program, treating seven patients suffering from acute respiratory failure and inflammatory complications associated with COVID-19 with Pluristem's PLX cells, in three medical centers in Israel.

### ***Patients' condition prior to the treatment with PLX cells***

All seven patients approved for treatment under compassionate use program with PLX cells exhibited, prior to treatment, respiratory failure due to ARDS, which is a major cause of mortality and required mechanical ventilation in an ICU. Four of the patients also demonstrated failure of other organ systems, including cardiovascular and kidney failure, indicating critical disease and poor prognosis.

### ***Preliminary data following treatment with PLX cells***

Six of the seven patients have completed the seven day follow up period ("Group A"). The seventh patient has not yet completed seven day follow up.

- While the treated patients are considered high risk for mortality (Pavan K. Bhatraju et al. <https://www.nejm.org/doi/full/10.1056/NEJMoa2004500>), the preliminary data demonstrated 100% survival rate as of today.
- Four patients (66%) out of Group A demonstrated improvement in respiratory parameters.
- Three patients (50%) out of Group A are in advanced stages of weaning from ventilators.
- One patient has shown no change in respiratory parameters, is still breathing with the assistance of a ventilator and remains relatively stable.
- One patient has shown deterioration in respiratory parameters.
- Two patients (50%) out of four in Group A with multi-organ failure prior to treatment, showed clinical recovery in addition to the respiratory improvement.

### ***Pluristem's COVID-19 clinical development strategy***

As a next step, the Company plans to apply for initiation of a multinational regulated clinical trial program for the potential use of PLX cells in the treatment of patients suffering from complications associated with COVID-19. In this regard, while Pluristem expects to continue treating patients for complications associated with COVID-19 under the compassionate use program in Israel, Pluristem does not intend to provide further updates on the status of this program and rather update on the status and progress of its contemplated clinical trial program.

"We are pleased with this initial outcome of the compassionate use program, and committed to harnessing PLX cells for the benefit of patients and healthcare systems. In order to maximize PLX cells' impact on patient recovery and to work towards making our treatment widely available, we plan to quickly move forward into a clinical development program. Pluristem is dedicated to using its competitive advantages in large-scale manufacturing to potentially deliver PLX cells to a large number of patients in significant need. We believe that research and governmental funding may be available to Pluristem to support the use of PLX cells for patients suffering from COVID-19 and are targeting such funding," stated Pluristem CEO and President, Yaky Yanay.

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### **PLX Cells for COVID-19**

PLX cells are available off-the-shelf and once commercialized, can be manufactured in large scale quantities, offering a key advantage in addressing a global pandemic. PLX cells are allogeneic mesenchymal-like cells that have immunomodulatory properties that induce the immune system's natural regulatory T cells and M2 macrophages, and thus may prevent or reverse the dangerous overactivation of the immune system. Accordingly, PLX cells may potentially reduce the incidence and/or severity of COVID-19 pneumonia and pneumonitis leading hopefully to a better prognosis for the patients. Previous pre-clinical findings of PLX cells revealed therapeutic benefit in animal studies of pulmonary hypertension, lung fibrosis, acute kidney injury and gastrointestinal injury which are potential complications of the severe COVID-19 infection. Clinical data using PLX cells demonstrated the strong immunomodulatory potency of PLX cells in patients post major surgery. Taken together, PLX cells' potential capabilities with the safety profile observed from clinical trials involving hundreds of patients worldwide potentially position them as a therapy for mitigating the tissue-damaging effects of COVID-19.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

### **Safe Harbor Statement**

This press release 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, Pluristem is using forward-looking statements when it discusses the interim results from the use of PLX cells on certain patients suffering from COVID-19, its expectation to continue treating patients for complications associated with for COVID-19 under the compassionate use program in Israel and its intention not to provide further updates on the status of this program and rather update on the status and progress of its contemplated clinical trial program, its plans to apply for initiation of a multinational clinical trial in order to maximize PLX cells' impact on patient recovery and to work towards making its treatment widely available, its dedication to using its competitive advantages in large-scale manufacturing to potentially deliver PLX cells to a large number of patients in significant need, its belief that research and governmental funding may be available to it to support its PLX cells for COVID-19 patients and its intent to target such funding, the potential of PLX cells in preventing or reversing the dangerous overactivation of the immune system, that PLX cells may potentially reduce the fatal symptoms of COVID-19 induced pneumonia and pneumonitis, and PLX cells' position as a therapy for mitigating the tissue-damaging effects of COVID-19. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem 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's products may harm recipients; changes in legislation may adversely impact Pluristem; 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 the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem 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 Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

### **Contact:**

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