
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): **June 9, 2014 (June 5, 2014)**

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)

31905

(Zip Code)

011 972 74 710 7171
(Registrant's Telephone Number, Including Area Code)

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))
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Item 7.01. Regulation FD Disclosure.

On June 5, 2014, the registrant issued a letter to its shareholders as of that date. The letter is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Warning Concerning Forward Looking Statements

Exhibit 99.1 to 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, we are using forward-looking statements, when we discuss that PLX-PAD cells may be effective in the treatment of muscle and tendon injuries, or when we discuss our clinical trials plans for various indications and when they will be announced, or when we discuss our expectation to initiate enrolment in South Korea for IC phase II study, or when we discuss continuing the work to set standards and garner government support for cell therapy and regenerative medicine, or when we discuss having further talks regarding cooperation and collaboration with the British government and UK-based companies, or when we discuss executing our long-term strategy to become the leader in the development and manufacture of a variety of "off-the-shelf" cell therapies. 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; 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 surgical 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 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 – Letter to the shareholders of Pluristem Therapeutics Inc. dated June 5, 2014.

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.

Date: June 9, 2014

By: /s/ Boaz Gur-Lavie
Name: Boaz Gur-Lavie
Title: Chief Financial Officer



Pluristem Issues Letter to Shareholders

HAIFA, ISRAEL, June 5th, 2014 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today issued a Letter to Shareholders from its CEO, Zami Aberman.

Dear Pluristem Shareholders,

We have started 2014 with strong momentum on many fronts, including advancements in our clinical pipeline and regulatory approvals surrounding our cell therapy production methods and new manufacturing facility.

The outstanding safety and efficacy results of our Phase I/II muscle injury study announced in January suggest that PLX-PAD cells may be effective in the treatment of muscle and tendon injuries. We analyzed the potential for a variety of orthopedic indications. Based on our findings and in keeping with our strategy, we have decided to move forward with at least two clinical indications, which will be announced in the next few weeks.

May was National Preeclampsia Awareness Month and we have been raising awareness for this potentially lethal disease of pregnancy for which there is no treatment. This tremendous unmet medical need makes preeclampsia one of our top priorities at Pluristem, and we are excited to advance our novel PLX-PAD cell therapy into clinical trials for this indication.

Enrollment of the Phase II intermittent claudication (IC) study is moving forward in the U.S., Germany and Israel and we expect to initiate enrollment in South Korea shortly.

Internally, we have enhanced our executive team by promoting Yaky Yanay to the position of President and Chief Operating Officer and appointing Boaz Gur-Lavie as Chief Financial Officer and Secretary. We are taking a leading role in industry-wide efforts to set standards and garner government support for cell therapy and regenerative medicine, and we will continue this work in the coming months. Pluristem supports the advancement of cell therapy through active participation in industry organizations, like the Alliance for Regenerative Medicine (ARM) and the International Society for Cellular Therapy (ISCT), that play a key role in shaping the future of the industry. Dr. Ohad Karnieli, Vice President of Development and Manufacturing, was recently confirmed as Chair of ISCT's Process and Product Committee for a two-year post.

Financial Update

- On May 11, 2014, Pluristem's common stock was added to the newly created TA Tech-Elite index on the Tel Aviv Stock Exchange. The TA Tech-Elite index comprises Israel's leading technology and biomed companies. The index includes 34 eligible companies with Pluristem comprising approximately 2.05% of the total value.

- Pluristem received approval for a 14.6 million New Israeli Shekel (approximately \$4.2 million) grant from the Office of the Chief Scientist (OCS) within the Israeli Ministry of Economy. The grant will be used to cover R&D expenses for calendar year 2014.

- As of the end of March, 2014 Pluristem's cash and cash equivalents totaled \$64.1 million.

Clinical Developments

- Preeclampsia

We submitted an application to the FDA requesting the Company's PLX-PAD cells be granted Orphan Drug Designation in the treatment of severe preeclampsia.

- In February we created a Preeclampsia Steering Committee, to advise the Company on the crafting of our clinical trials, from the design of the study protocol to processing patient feedback and generating the final study report. Committee members are leaders in the field of preeclampsia and have a deep commitment to finding a treatment.

- Acute Radiation Sickness

The U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), has commenced a mechanism-of-action study of our second product, PLX-RAD cells, for the treatment of acute radiation syndrome (ARS). The study aims to investigate the effects of PLX-RAD cells on body weight, blood count parameters, cytokine concentrations and bone marrow or spleen cellularity at various time points following the administration of PLX-RAD cells to animals receiving total body irradiation.

Regulatory Approvals for 3D Cell Manufacturing Process & Facility

- United States

The FDA has reviewed comparability studies of our PLX cell products and granted Pluristem approval to use cells manufactured at our new state-of-the-art facility in Haifa, Israel for clinical trials in the U.S.

- South Korea

The South Korean Ministry of Food and Drug Safety (MFDS) has approved our proprietary method for 3D commercial-scale cell expansion. With this approval, we may now commence our Phase II Intermittent Claudication trial in Korea using cells manufactured at our Haifa facility. This study was approved by the MFDS in November 2013; the trial is ongoing in the U.S., Germany and Israel.

- European Union

Our new manufacturing facility has also received the European Union's Qualified Person Declaration. With this declaration, we are now approved to use cell therapies manufactured at our Haifa facility in all phases of our clinical trials conducted in the European Union.

Industry Leadership

- We have been working with the Alliance for Regenerative Medicine (ARM), an industry organization, to help bring about a legislative, funding, and reimbursement environment that can accelerate the commercialization of breakthrough cell therapies which have the potential to transform the lives of patients in need. In April, our executives met with members of congress to generate bipartisan support for bills in the Senate and House of Representatives that promote the value of regenerative medicine.

- Pluristem recently hosted a delegation from the United Kingdom at our headquarters in Haifa. Officials visiting Pluristem included the UK's Minister for Universities and Science, David Willetts, whose responsibilities include overseeing the Department of Business Innovation and Skills (BIS), and Dr. Stephen Ward, Chief Operating Officer of the Cell Therapy Catapult, a non-profit organization which aims to grow the UK cell therapy industry. We look forward to further talks regarding cooperation and collaboration with the British government and UK-based companies.

Our performance over these past months clearly reflects Pluristem's strengths across our clinical pipeline, our commitment to our intellectual property, our proprietary in-house manufacturing capabilities and the dedication of our staff. We will continue to build on these achievements to successfully execute our long-term strategy to become the leader in the development and manufacture of a variety of "off-the-shelf" cell therapies.

Thank you for your support.

Zami Aberman
Chairman & CEO

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapies. The Company's patented PLX (PLacental eXpanded) cells are a drug delivery platform that releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory and ischemic diseases. PLX cells are grown using the Company's proprietary 3D micro-environmental technology and are an "off-the-shelf" product that requires no tissue matching prior to administration.

Pluristem has a strong intellectual property position, Company-owned GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team. For more information visit www.pluristem.com, the content of which is not part of this press release.

Safe Harbor Statement

This press release 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, we are using forward-looking statements, when we discuss proposed legislation that may accelerate bringing cell therapies to the market, its adoption, if adopted at all and effect on the Company. 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; 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 surgical 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 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.

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