PLURISTEM THERAPEUTICS INC
Form DEFA14A
May 16, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

SCHEDULE 14A

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant ý

Filed by a Party other than the Registrant ¨

Check the appropriate box:

¨ Preliminary Proxy Statement.

¨ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2)).

¨ Definitive Proxy Statement.

ý Definitive Additional Materials.

¨ Soliciting Material Pursuant to §240.14a-12.

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

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

ý No fee required.

¨ Fee computed on table below per Exchange Act Rules
14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

---

(5) Total fee paid:

.. Fee paid previously with preliminary materials.

oCheck box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

May 16, 2011

Dear Shareholder,

2011 has been a very exciting year so far for Pluristem Therapeutics, highlighted by a number of significant achievements. I would like to share with you a few of our year's main milestones and some of the upcoming activities.

Clinical Development

In January, we successfully completed a parallel scientific advisory process with the European Medicines Agencies (EMA) and the US Food and Drug Administration (FDA) that will allow us to pursue our comprehensive approach towards the treatment of two major components of peripheral artery disease (PAD), intermittent claudication (IC) and critical limb ischemia (CLI), with our placenta-derived PLX cells.

Pluristem's comprehensive clinical plan includes a Phase II multinational IC study that will enroll subjects suffering from a less severe form of PAD, a potentially preventive treatment which may have an impact on the disease progression. In addition, the company is aiming for a CLI Phase II/III multinational pivotal study with the primary endpoint of major-amputation free survival rate following 12 months of follow-up.

In both the CLI and IC studies our PLX-PAD cells will be injected twice, four months apart. Pluristem's cells are an allogeneic therapy, require no tissue matching prior to administration, allowing no pre-treatment discomfort and are an “off the self” product. We expect the Phase II IC study to enroll approximately 180 patients and the Phase II/III CLI study to enroll approximately 450 patients. Both studies will include a control group. The clinical sites which participated in our earlier Phase I studies will take part in the upcoming studies and currently we are in the process of selecting additional sites.

The studies will begin once the protocol design is finalized, upon regulatory approval and upon completion of vendor selection to support the study (for example: monitoring, data management and pharmacovigilance).

Pluristem announced in April 2011 that six month clinical follow-up data from its two open-label, dose-escalation, Phase I clinical trials conducted in the US and Germany suggest PLX-PAD is safe, improves quality of life and is potentially effective in treating CLI patients. Among the 27 patients treated with PLX-PAD, only one amputation was recorded at the six months follow-up representing a 3.7% amputation rate. This represents a 75% reduction in the amputation rate compared to historical data, which varies from 20-40%.

Pluristem is also focused on scaling up its proprietary three-dimensional (3D) cell manufacturing platform from pilot to a commercial production stage. Our up-scaled bioreactor system is capable of manufacturing millions of PLX doses originating from different placentas. Our manufacturing process has demonstrated batch to batch consistency, an important manufacturing component of biological products. In addition, scalable manufacturing is one of the major challenges cell based products are facing. Pluristem's unique chemistry, manufacturing and controls (CMC) was described in detail during the EMA and FDA advisory meeting and was accepted as a valid, scalable manufacturing process. I strongly believe that our 3D cell manufacturing platform will be a major advantage for us as we begin marketing our product.

Pre Clinical Pipe Line and R&D

In March 2011, Pluristem and the Berlin-Brandenburg Center for Regenerative Therapies (BCRT), in cooperation with the Charité - University of Medicine in Berlin, announced the results of a preclinical study demonstrating significant improvement in the recovery of muscle function, when compared to controls, following the local administration of PLX cells in a muscle injury mice model . This study suggests that Pluristem's PLX cells have the potential to treat muscle injuries caused by surgery or accident. Subject to regulatory approval, Pluristem intends to move ahead with the first clinical trials for muscle injury indications.

Over the last few months, Pluristem has also established important R&D partnerships with NYU Medical Center for the study of PLX cells in the treatment of diabetic foot ulcers and with Hadassah University Medical Center to continue a previously conducted animal study indicating that PLX cells are potentially effective in the treatment of radiation sickness. Pluristem expects for a successful outcome of these preclinical studies to potentially lead to new therapies.

We will continue to collaborate with universities and academic institutions in the US, Europe and Israel to fully leverage the uniqueness of our cells and explore their use in other indications.

Financial status

On February 1, 2011, we announced the completion of a secondary capital raise, with net proceeds of over $38 million. This raise came after Pluristem announced the dual listing of its shares for trading on the Tel Aviv Stock Exchange. I believe that the increase of trading hours and the versatility of our investor base will continue to contribute to an increased interest in and trading activity of our stock. Data from our last financial report released on May 11, 2011 demonstrated a strong balance sheet with over $44 million in cash and cash equivalents on March 31, 2011. We anticipate our burn rate of cash over the next 12 months will increase as our clinical activities progress. We believe that the capital we currently have will enable the company to support its planned activities at least until the end of calendar year 2013.

Business Development

I am very pleased to see the enhanced business development activity in the cell therapy area, the progress our peer companies have made in their respective clinical trials, the relationships they have established and their market appreciation. Since the announcement of our planned IC and CLI studies, Pluristem has also received indications from several pharmaceutical companies expressing an interest in discussing licensing agreements to establish partnerships for the development of cell based therapies. It is the intent of Pluristem's management to consider partnerships, depending on the partnership's benefits to Pluristem and its shareholders. We believe our “off-the-shelf” product candidates, our scalable 3D cell manufacturing platform that supports the mass production of cells, and our financial position place us in a very good position to potentially cooperate with the right partners, under the right deal structure, for different clinical indications.

Our business development strategy includes establishing partnerships with universities and academic institutions, taking advantage of Pluristem's expertise in manufacturing high quality cells and the institution's expertise in preclinical models. Pluristem's policy is to retain ownership of the intellectual property on PLX cells in these partnerships. Additionally, collaborating with pharmaceutical companies is in line with our business development strategy.

While 2011 has been a great year so far for Pluristem in terms of developing our entire product line, our most exciting achievement is our belief that we are much closer to effectively treating patients suffering from peripheral artery disease. With the advantages of our PLX cells and the expertise of our company personnel, I am confident that Pluristem will become the leader in cell therapy for peripheral vascular disease.

Thank you very much,

Zami Aberman
Chairman & CEO

# # #

About Pluristem Therapeutics Inc.

Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR) is a leading developer of placenta-based cell therapies. The company's patented PLX (PLacental eXpanded) cells drug delivery platform releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory 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. Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in nerve pain and muscle damage, when administered locally, and in inflammatory bowel disease, MS and stroke, when administered systemically.

Pluristem has a strong patent portfolio, GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team.

For more information visit www.pluristem.com, or follow us on Twitter@Pluristem, the content of which is not part of this letter.

Contact:
Pluristem Therapeutics Inc.
William Prather R.Ph., M.D.
Sr. VP Corporate Development
1-303-883-4954
William.PratherMD@pluristem.com

Daya Lettvin, Director
Investor & Media Relations
+972-54-674-5580
daya@pluristem.com

Media Contact:

Matthew Krieger
Ruder Finn – for Pluristem
+972-54-467-6950
matthew@ruderfinn.co.il

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 speak about the competitive advantages of our platform, or when we say that Phase I clinical trials suggest PLX-PAD is safe, improves quality of life, and is potentially effective in treating patients, or when we say that Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in nerve pain and muscle damage when administered locally and in inflammatory bowel disease, MS, stroke and radiation exposure when administered systemically, the expected development of our products, our plans, intentions or expectations regarding clinical trials, our expectations regarding our short and long-term capital requirements and sufficiency of our capital resources, our outlook for the coming months and information with respect to any other plans, collaboration with other companies and institutions and strategies for our business. These forward-looking statements 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 our clinical trials; 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; 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. 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, 2010 and in other reports Pluristem files from time to time with the Securities and Exchange Commission.