

#### **MARKET STATISTICS**

| Exchange / Symbol        | NasdaqCM:PSTI   |
|--------------------------|-----------------|
| Price:                   | \$1.33          |
| Market Cap (\$mm):       | \$106.61        |
| Enterprise Value (\$mm): | \$68.64         |
| Shares Outstanding (mm): | 80.16           |
| Float (%):               | 93%             |
| Volume (3 month avg.):   | 132,400         |
| 52 week Range:           | \$0.71 - \$2.52 |
| Industry:                | Biotechnology   |

#### **CONDENSED BALANCE SHEET**

(\$mm, except per share data)

| <b>Balance Sheet Date:</b> | 3/31/2016 |
|----------------------------|-----------|
| Cash & Cash Equivalent:    | \$37.97   |
| Cash/Share:                | \$0.47    |
| Equity (Book Value):       | \$43.11   |
| Equity/Share:              | \$0.54    |

#### **CONDENSED INCOME STATEMENTS**

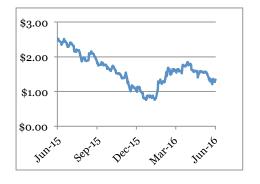
(\$mm, except per share data)

| FY 06/30 | Revenue | Income   | Adj.<br>EBITDA | EPS      |
|----------|---------|----------|----------------|----------|
| FY13     | \$.679  | \$(21.2) | \$(18.4)       | \$(0.38) |
| FY14     | \$.379  | \$(26.9) | \$(20.1)       | \$(0.42) |
| Fy15     | \$.379  | \$(24.7) | \$(19.1)       | \$(o.35) |
| FY16E    | \$2.85  | \$(24.3) | \$(19.4)       | \$(0.31) |

#### LARGEST SHAREHOLDERS

| Zami Aberman                   | 1,929,700 |
|--------------------------------|-----------|
| Yaky Yanay                     | 1,218,100 |
| Renaissance Technologies Corp. | 1,006,800 |
| Barclays Bank PLC.             | 818,700   |
| Harel PIA Mutual Fund Ltd.     | 647,700   |
| Doron Shorrer                  | 502,800   |
| Israel Ben Yoram               | 326,500   |
| Hava Meretzki                  | 317,700   |
| Isaac Braun                    | 317,700   |

### **STOCK CHART**





Laura S. Engel, CPA laura@stonegateinc.com 214-987-4121

## **COMPANY DESCRIPTION**

Founded in 2001, Pluristem Therapeutics, Inc. is a clinical-stage biotechnology company focused on regenerative therapeutics. Its technology involves converting cells derived from human placentas into patented PLX (PLacental eXpanded) cells using its proprietary three-dimensional bioreactor platform. The PLX cells are programmed to release therapeutic proteins in response to inflammatory, ischemic and hematological conditions. The cells can be used as "off-the-shelf" products—they require no tissue matching prior to administration. They can be produced in commercial quantities in Pluristem's GMP-certified manufacturing facility. The Company's clinical-stage products, PLX-PAD and PLX-R18, address indications in multi-billion dollar markets, including cardiovascular, orthopedic, pulmonary, hematological, and women's health conditions. Pluristem employs approximately 170 people and is headquartered in Haifa, Israel.

#### **SUMMARY**

The combination of a pipeline of products that address large patient populations with critical unmet needs, positive data that validate its therapies, strategic partnerships, and an experienced management team working closely with global regulatory agencies, is opening doors for early entry into markets in the U.S. and abroad. To date, the Company has completed three clinical trials with successful results, and three pivotal trials are planned to begin in 2016. Pluristem is well-positioned to be a global leader in regenerative medicine for the following reasons:

- Pluristem has a broad platform with its patented PLX cells that are engineered
  to secrete a specific cytokine secretion profile, targeting different indications,
  most of which address sizable market opportunities with limited or no
  treatment options.
- The Company's unique manufacturing technology addresses the limitations of the standard process of manufacturing cell therapies. Using proprietary bioreactors to simulate the 3D structure of the body, the self-controlled, fully computerized platform is many times more efficient than current 2D methods. The platform is scalable, cost effective and capable of creating 150,000 doses of commercial grade cells annually with consistent quality.
- The Company-owned, GMP-certified manufacturing and research facility is approved by the FDA, as well as the German, EU, South Korean, Japanese and Israeli regulatory agencies for Phase II, III trials and marketing.
- One of Pluristem's most compelling advantages is its extensive intellectual property portfolio consisting of over 60 issued patents and over 150 pending applications in the U.S., Europe, China, Japan, Israel, South Africa, South Korea, Mexico, Russia and South America.
- PSTI is exploiting regulatory programs in the EU and Japan that provide accelerated pathways to near-term commercialization. Using results from two successful Phase I trials in critical limb ischemia (CLI), Pluristem was accepted into both regulatory programs (and no other company in the world has been accepted into both programs). These programs could allow the Company to bypass Phase III trials and tens of millions of dollars in development costs. The Company is slated to initiate pivotal trials in 2016, which could lead to commercialization authorization late 2018 or early 2019.
- Using the FDA Animal Rule, the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID) has initiated studies in large animals to assess the proper dosage for PLX-R18. The Animal Rule eliminates the need for clinical efficacy trials in humans (Phases II and III typically), and approval could come quickly, possibly in 2017.
- In Q4 2015, the FDA granted Orphan Drug status to Pluristem's product for preeclampsia, a potentially life threatening condition in pregnant women for which there is no treatment except delivery. Orphan Drug designation generally accelerates the time to market, and provides a seven-year market exclusivity period.
- Utilizing discounted flow analysis of the CLI opportunity alone, we arrive at a valuation range of \$5.51 \$6.27, with a midpoint of approximately \$6.



#### **BUSINESS OVERVIEW**

Pluristem is well-positioned in the high-growth regenerative medicine market with demonstrated success in a number of indications. The Company is pursuing a disciplined strategy focused on leveraging its intellectual property and proprietary technology to target regulatory pathways that will reduce costs and time to market for its product candidates. The Company's core growth strategy includes:

- Seeking opportunities for accelerated paths to market
- Pursuing partnering and collaboration arrangements to advance its technology and therapeutic products
- Using its R&D capabilities and technology to create additional product candidates

Accelerated regulatory paths to market - Recent developments provide Pluristem with the opportunity to accelerate its path to market, while lowering the cost of the approval process for its PLX cell therapies. In May 2015, European Medicines Agency (EMA) selected the PLX cell program relating to the treatment of critical limb ischemia, to participate in the Adaptive Pathways pilot project. This pathway will enable the Company to obtain extra guidance and support through additional meetings and more aptly prepared for the pivotal Phase II trial in Europe with sites in the US. The pivotal Phase II trial is expected to start this year.

In January 2016, Japan's Pharmaceutical and Medical Devices Agency (PMDA) gave approval for Pluristem to begin a pivotal trial of PLX-PAD on 75 CLI patients, which is a significant step forward in the pathway created under the Regenerative Medicine Law in Japan. The trial has not yet been started, but if results are positive, Pluristem can apply for approval to market the product to CLI patients. Under this approach, the Company will bypass spending years and millions of dollars on Phase III trials, and will collect "real world" data while marketing the product.

Acceptance into the accelerated pathways of these two countries, both leaders in regenerative medicine, is a critical milestone that adds validation to the Company's processes and products. Going forward, positive data showing PLX-PAD to be safe and effective will not only lead to top line revenues, but also should elevate Pluristem's position in the industry, capturing the attention of potential strategic partners. Conditional market approval in both Japan and Europe could come in late 2018 to early 2019.

**Partnerships and collaborations** - Another key component of Pluristem's growth strategy is collaborating with government, research/clinical institutions and companies to share the costs of developing and marketing its products. The Company is collaborating with CHA Biotech Co., Ltd., a South Korean conglomerate, to develop PLX-PAD for the treatment of intermittent claudication and critical limb ischemia. CHA is conducting studies in South Korea, and if the product receives approval, the two companies will create a 50/50 joint venture to market Pluristem's products in South Korea.

Pluristem is also collaborating with government regulators from around the world. In February 2016, the National Institute of Allergy and Infectious Diseases, which is part of the U.S. National Institutes of Health, agreed to initiate large animal studies to test the dosing of PLX-R18 as a countermeasure for hematologic effects of acute radiation syndrome. Once the most effective dose has been determined, a pivotal trial could be initiated, with results used to validate a license application submission of PLX-R18 as a treatment for ARS under the Animal Rule regulatory path (a program that provides for licensure when human studies are not feasible or ethical. Fukushima Medical University is collaborating with Pluristem to ultimately treat people exposed to radiation. In addition, at year-end 2015, Pluristem signed a memorandum of understanding with the Fukushima Global Medical Science Center to develop PLX-R18 to treat ARS and the negative effects of radiotherapy in cancer patients.

Creating additional collaborations and partnerships will continue to be Pluristem's focus as the new programs in Europe and Japan, and other ongoing programs relating to PLX products, present the Company with multiple opportunities.

Manufacturing and technology - A central theme behind Pluristem's cell therapy program is the belief that controlling the process—from acquiring the placental cells to delivery to the patient—is essential to making the program commercially successful.

Exhibit 1: Pluristem's PLX Cell Expansion Technology



Source: Company Reports

PLX cells contain mesenchymal-like adherent stromal cells derived from an uncontroversial source: donated full-term human placenta tissue that is normally discarded following a birth. Placental cells are optimal for triggering a healing response because they are immunoprivileged—they do not induce an immunological response from the body, which makes them available for any purpose without the necessity of histocompatibility between the donor and recipient tissue.



The manufacturing of PLX cells begins in the Company's cGMPcompliant facilities with automated proprietary bioreactors, which create a 3D environment using synthetic polystyrene and polypropylene scaffolds. The structure of the bioreactors is designed to imitate the natural three-dimensional structure of the human body to optimize the expansion and modification of the stromal cells. The 3D process enables large-scale production of PLX cells for a fraction of the cost of the standard methods. Cells harvested from the placenta are doubled up to twenty five times (typically much less due to efficiency of cell type), enabling the cells from one placenta to treat approximately 20,000 patients. The process time is approximately eight weeks, and the PLX cells have a shelf life of 36 months. The Company's production facility, located in Haifa, Israel, is capable of manufacturing 150,000 doses of PLX cells per year, with complete batch-to-batch consistency.

The PLX cells are designed to release therapeutic chemokines, cytokines and growth factors that respond to local and systemic signals produced by patients with ischemic and inflammatory and hematological conditions. The secreted therapeutic factors reach the damaged tissue through the bloodstream, initiating the healing process. PLX cells can be customized to secrete differing cytokine profiles to target different indications. In a sense, by changing the culture conditions, Pluristem "educates" the placental cells to produce specific types of growth factors based on specific indications. Tightly monitoring the conditions in culture systems allows for new product development and reproducibility, resulting in an extensive therapy product pipeline.

## **CLINICAL DEVELOPMENT**

Current product candidates include: (1) PLX-PAD cells, for use in cardiovascular, orthopedic, pulmonary, and conditions relating to women's health, and (2) PLX-R18 cells for use in hematological diseases treating bone marrow damaged by various diseases, malignant and non-malignant cancer treatment and radiation exposure.

#### **PLX-PAD**

**Critical limb ischemia** - CLI is a severe obstruction of the arteries, which markedly reduces blood flow to the extremities (hands, feet and legs), affecting approximately 2M people in the US, with that number expected to climb to 2.8M by 2020. In Western Europe, the population affected is estimated at 3M and expected to increase to 4m by 2030. In about 10%-40% of patients, amputation of the limb becomes unavoidable, and approximately 20% die within the first year of diagnosis.

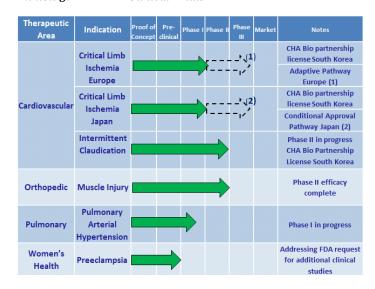
Exhibit 2: CLI Arterial Blockage



Source: Company Reports

Pluristem has completed two Phase I safety clinical trials, one in the U.S. and one in Germany. The studies demonstrated the product is safe with no blood type or antigen matching required. Additionally, PLX-PAD shows effectiveness in reducing the frequency of deaths and amputations in CLI patients. Pooled data from two studies showed 85% amputation free survival (AFS) rate at one year, versus AFS of 66.8% based on placebo groups from other trials, a risk reduction of approximately 59%.

Exhibit 3: PLX-PAD Clinical Trials



Source: Company Reports

Intermittent claudication — Intermittent claudication is a symptom of peripheral arterial disease and involves a tight, aching, or squeezing pain in the calf, foot, thigh, or buttock that occurs during exercise but is relieved by rest. Pluristem has completed enrollment of 150 patients in its Phase II trial in the U.S., Germany, Israel and South Korea to assess PLX-PAD in IC patients; the trial will enroll a total of 170 in 2016, and results are expected in 2017.



**Muscle regeneration following a hip replacement** - Hip replacement surgery is one of the most widely performed procedures in the U.S., with 332,000 procedures performed every year, according to the CDC. One of the consequences of the surgery can be damage to the gluteal muscles.

The Company has completed a Phase I/II double-blind study in Germany to assess the safety and efficacy of PLX-PAD cells for the regeneration of gluteal musculature following a total hip replacement. The findings strongly suggest that PLX-PAD cells could be used to improve soft tissue regeneration. The study met its primary efficacy endpoint, with PLX-PAD treated patients showing substantial improvement of maximal voluntary muscle contraction force (500% increase in traction force) and volume (300% increase) at 26-week post-operative follow-up versus the group. In addition to statistically significant improvement in muscle force of the operated hip, the patients' contralateral hips showed rejuvenation, which the researchers speculated was the result of the systemic effect of PLX-PAD cells. Pluristem is in discussions with the EMA concerning several indications for potential development of orthopedic indications through the European Union's Adaptive Pathways project.

Preeclampsia — At year-end 2015, the FDA granted an Orphan Drug designation to Pluristem for the use of PLX-PAD cells to treat severe preeclampsia, a condition for which there is no treatment, which leads to excessively high blood pressure in 6%-8% of pregnant women and can be fatal to both the mother and the fetus. Generally, the FDA reviews treatments that carry Orphan Drug status faster, which can accelerate the time to market approval. Additionally, the designation will provide Pluristem with a seven-year period of exclusivity in the market and increased access to grants and tax credits. Importantly, the designation provides another validation of Pluristem's therapeutic technology. The FDA granted Orphan Drug status based on a preclinical study showed that PLX-PAD cells were able to normalize or significantly lower all the key symptoms of preeclampsia in two mouse models of the disease with only one intramuscular dose.

Pulmonary arterial hypertension (PAH) — is increased pressure in the pulmonary arteries, the arteries that carry blood from your heart to your lungs to pick up oxygen. PAH causes symptoms such as shortness of breath during routine activity, tiredness, chest pain, and a racing heartbeat, and as the condition worsens, its symptoms may limit all physical activity. In 2013, Pluristem and its former licensing partner, United Therapeutics, initiated a single arm, Phase I trial using PLX-PAD for the treatment of pulmonary arterial hypertension. The results from the initial cohort showed a good safety profile, with an encouraging efficacy trend, and PSTI awaits data on the second cohort (although the trial is no longer active). The Company is open to collaborating with other licensing partners to move forward with the clinical development of the PAH program.

## PLX-R<sub>1</sub>8

Pluristem's second cell product in development, PLX-R18, is the result of the research team's discovery that placenta cells have unique properties to help the body recover from exposure to radiation. By secreting a range of proteins that activate the resurgence of progenitor cells in the bone marrow, PLX-R18 is

expected to support the recovery of blood cell production in bone marrow that is impaired by a variety of causes including some types of cancer and cancer treatments and acute radiation syndrome (ARS). Importantly, the mechanism of action has the potential to treat a wide range of hematologic indications, exposing Pluristem to multiple global market opportunities. The Company's first three indications relate to regeneration of bone marrow function after exposure to high levels of radiation, such as after a nuclear disaster, incomplete engraftment of a hematopoietic cell transplantation, or bone marrow transplant failure.

Exhibit 4: PLX-R18 Clincial Trials

| Therapeutic<br>Area | Indication                                  | Proof of<br>Concept | 333333333333333333333333333333333333333 | Phase I | Phase II | Phase<br>III | Market | Notes  |
|---------------------|---|---------------------|---|---------|----------|--------------|--------|--|
| Bone Marrow R S     | Bone Marrow<br>Transplant<br>Failure        |                     |   |         |          |              |        | Compassionate use treatment (with PLX-PAD)   |
|                     | Acute<br>Radiation<br>Syndrome              |                     | $\Rightarrow$                           |         |          |              |        | Supported by NIAID Animal<br>Rule Pathway – Pivotal Study<br>Underway                                    |
|                     | Support<br>Hematopoietic<br>Cell Transplant |                     | $\Rightarrow$                           |         |          |              |        | Umbilical cord blood,,<br>peripheral blood cell, bone<br>marrow transplantation –<br>Cleared for Phase I |

Source: Company Reports

Acute Radiation Syndrome - Acute Radiation Syndrome (ARS) - In preclinical studies completed by the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID), animals given extremely high doses of radiation, and then treated with PLX-R18, have shown nearly 100% recovery, compared with 30% recovery in animals in the control group. The mice treated with the therapy improved production of all three blood lineages: red cells, white cells and platelets. The NIAID also completed a study of the mechanisms of action of the PLX cells. PLX-R18 could potentially save lives in the event of another nuclear power plant accident or a nuclear attack. The NIAID has initiated a large animal dose evaluation study that is intended to be the basis for a large animal pivotal trial. Because the product is being developed under the FDA's Animal Rule, there are no efficacy trials in humans. Pluristem could apply for approval as soon as 2017. If PLX-R18 is approved, the government may begin stockpiling the PLX-R18 for use in the treatment of exposure to high levels of radiation. According to management, the NIAID has been positive about their study results to date, and Pluristem would be capable of producing thousands of doses of the PLX-P18 radiation antidote to use in case of a nuclear threat. PLX cells are well suited for stockpiling and rapid initiation of treatment; the off-the-shelf-cells can be injected quickly using a standard syringe because they do not require tissue matching.



Support Hematologic Cell Transplant - Bone marrow failure occurs when bone marrow fails to produce a sufficient number of platelets, white or red blood cells, and is caused by medical conditions such as aplastic anemia and hematologic malignancies, or as a side effect of cancer treatments. The only cure is a hematopoietic cell transplant (HCT), and if the transplantation results in incomplete engraftment, the patient can die. In January 2016, the Company received FDA clearance to begin a Phase I trial for treating incomplete hematopoietic recovery following hematopoietic cell transplantation. The clearance was based on a study demonstrating that mice with damaged bone marrow that received intramuscular injections of Pluristem stem cells (PLX-R18) together with a bone marrow transplant showed significantly faster recovery of blood cell production than those mice given a placebo with their bone marrow transplant.

Bone Marrow Transplant Failure - The Company intends to test the effect of PLX-R18 in regenerating bone marrow function in patients whose bone marrow transplants have failed. Pluristem's in-house manufacturing capability puts the Company in a position to compete with Amgen's (NASDAQ: AMGN) cancer drug Neupogen®, a drug that increases white blood cells in cancer patients receiving chemotherapy and radiation therapy. Neupogen has been approved to counteract a hematopoietic component of ARS, and Amgen has been granted a \$157.5 million contract with the U.S. Dept. of Health and Human Services' Project Bioshield to manage, rotate and replenish an ARS stockpile. Comparing the two therapies, Neupogen increases white blood cell count, while PLX-P18 increases white and red blood cells, as well as platelets, a key advantage for Pluristem's therapy. Another possible advantage is the PLX-P18 systemic mechanism of action, which suggests that the therapeutic could potentially work beyond the hematopoietic component of ARS to treat multiple organs that can be damaged as part of the syndrome. Although it is early in the process, Pluristem may have the opportunity to capture some lucrative contracts with recurring revenue streams.

Exhibit 5: Collaborations on Acute Radiaiton Syndrome

| Government &<br>Academic                              | Indication               | Deal structure  |  |  |
|---|--------------------------|---|--|--|
| National Institute of Allergy and Infectious Diseases | Acute Radiation Syndrome | U.S. National Institutes of<br>Health (NIH) Support for<br>Development of PLX-R18   |  |  |
| Fukushima<br>Medical University                       | Acute Radiation Syndrome | Pluristem will contribute cells<br>and scientific knowledge, FMU<br>will conduct the studies and<br>provide the required resources. |  |  |

Pluristem keeps IP and manufacturing rights in all collaborations

Source: Company Reports

#### **INDUSTRY OVERVIEW**

According to research firm Frost and Sullivan, the stem cell therapy market, which is the fastest growing segment of the regenerative medicine market, is expected to reach \$40 billion by 2020 and \$180 billion by 2030. The market is driven by demonstrated successes in treating life-threatening diseases, combined with increasing demand from an aging global population. At the same time, growth in the stem cell market has been constrained by the high cost of building cGMP compliant facilities, increasing industry regulations, and the lack of standardization. There is cause for concern when considering that if just 20% of the approximately 318 late-stage global product candidates are approved, there will be a shortage of stem cell therapy processing facilities to supply the 64 approved products. Pluristem's manufacturing facility, which is approved by authorities in the U.S., Israel, South Korea, Japan and the EU, provides the Company with a major advantage, enabling the reliable production of standardized, high-quality commercial quantities of stem cells quickly and cost effectively.

While the U.S. and Europe account for approximately threequarters of the regenerative medicine market, Japan and South Korea are making significant contributions to the field in terms of emphasizing research and adoption of the technology, making the Asia-Pacific region the fastest growing region going forward. Pluristem has made strong inroads into all of these markets, which should open the door to longer-term opportunities.

### **RISKS**

Pluristem is a developmental stage company with multiple products at various stages of regulatory approval. None of the products has been approved, and none has been tested in latephase trials. While some products may be able to bypass years of clinical trials to get to commercialization, the Company's first product approvals could still take years, requiring the Company to raise additional capital. Additionally, Pluristem competes with several very large pharmaceutical and biopharmaceutical companies in the stem cell therapeutics market, some of which may address indications for which Pluristem has developed therapies.



# **INCOME STATEMENT**

Pluristem Therapeutics, Inc. (NasdaqCM: PSTI)
Consolidated Statements of Income (in thousands \$, except shares and per share amounts)
Fiscal Year: June

|  | FY 2013  | FY 2014   | FY 2015  | FY 2016 E  |
|--|--|---|--|--|
| Revenues   | 6.70   | 0.00  |  |  |
| Revenues   | \$ 679   | \$ 379  | \$ 379   | \$ 2,3   |
| otal revenue   | 679  | 379   | 379  | 2,5  |
| ost of revenues  |  |   |  |  |
| Cost of sales  | (20)   | (11)  | (13)   |  |
| Total cost of revenues   | (20)   | (11)  | (13)   |  |
| Gross (loss) profit  | 659  | 368   | 366  | 2,   |
| Operating expenses   |  |   |  |  |
| Research and development expenses  | (19,906)   | (24,938)  | (23,416)   | (22,   |
| Participation by the OCS and other parties   | 2,673  | 5,396   | 4,243  | 1,   |
| Research and development expenses, net   | (17,233)   | (19,542)  | (19,173)   | (21,   |
|  |  |   | ` ' '  |  |
| General and administrative expenses  | (5,649)  | (8,676)   | (6,460)  | (6,  |
| otal operating expenses  | (22,882)   | (28,218)  | (25,633)   | (27,   |
| ncome (loss) from operations   | (22,223)   | (27,850)  | (25,267)   | (24,   |
| Financial income (expense), net  | 1,068  | 918   | 590  |  |
| otal other income (expense):   | -  | 918   | 590  |  |
| re-tax income (loss)   | (21,155)   | (26,932)  | (24,677)   | (24,   |
| Provision for taxes (benefit)  |  |   |  |  |
| fet income (loss)  | (21,155)   | (26,932)  | (24,677)   | (24,   |
| ` '  |  | ` ' '   |  |  |
| let income (loss) applicable to common stockholders  | \$ (21,155)  | \$ (26,932)   | \$ (24,677)  | \$ (24,  |
| asic EPS (loss)<br>biluted EPS (loss)  | \$ (0.38)<br>\$ (0.38)   | \$ (0.42)<br>\$ (0.42)  | \$ (0.35)<br>\$ (0.35)   | \$ (0<br>\$ (0   |
| easic shares outstanding   | 55,481,357   | 63,514,405  | 70,284,337   | 79,686,  |
| Diluted shares outstanding   | 55,481,357   | 63,514,405  | 70,284,337   | 79,686,  |
| nuted snares outstanding   | 33,481,337   | 63,314,403  | /0,284,337   | /9,080,  |
| EBITDA   | \$ (21,190)  | \$ (25,948)   | \$ (23,193)  | \$ (22,  |
| EBITDA adjusted for other non-cash charges   | \$ (18,391)  | \$ (20,097)   | \$ (19,141)  | \$ (19,  |
| adjust EBITDA per diluted share  | \$ (0.33)  | \$ (0.32)   | \$ (0.27)  | \$ (0  |
|  |  |   |  |  |
| Iargin Analysis<br>ross margin   | 97.1%  | 97.1%   | 96.6%  | 96.5%  |
| Lesearch and development expenses, net   | 2538.0%  | 5156.2%   | 5058.8%  | 741.9%   |
| General and administrative expenses  | 832.0%   | 2289.2%   | 1704.5%  | 220.3%   |
|  | -3272.9%   | -7348.3%  | -6666.8%   | -865.7%  |
| Operating margin   |  |   | -61.19525066   | -865.7%<br>-791.2%   |
| DITD A manain  | 2120.00/   |   |  | -/91.2%  |
| -  | -3120.8%   | -6846.4%  |  |  |
| djusted EBITDA   | -2708.5%   | -5302.6%  | -5050.4%   | -680.4%  |
| djusted EBITDA   |  |   |  | 1  |
| djusted EBITDA let income margin Growth Rate Analysis Y/Y  | -2708.5%<br>-3115.6%   | -5302.6%<br>-7106.1%  | -5050.4%<br>-6511.1%   | -680.4%<br>-855.0%   |
| djusted EBITDA<br>let income margin<br>Growth Rate Analysis Y/Y<br>otal revenue  | -2708.5%<br>-3115.6%<br>N/A                                    | -5302.6%<br>-7106.1%  | -5050.4%<br>-6511.1%   | -680.4%<br>-855.0%<br>651.2%   |
| djusted EBITDA let income margin  Growth Rate Analysis Y/Y otal revenue otal cost of revenues  | -2708.5%<br>-3115.6%<br>N/A<br>N/A                             | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%   | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%   | -680.4%<br>-855.0%<br>651.2%<br>-669.2%  |
| Adjusted EBITDA  Net income margin  Growth Rate Analysis Y/Y  Total revenue  Total cost of revenues  | -2708.5%<br>-3115.6%<br>N/A                                    | -5302.6%<br>-7106.1%  | -5050.4%<br>-6511.1%   | -680.4%<br>-855.0%<br>651.2%   |
| Adjusted EBITDA  Jet income margin  Growth Rate Analysis Y/Y  Jotal revenue  Jotal cost of revenues  Jesearch and development expenses, net  | -2708.5%<br>-3115.6%<br>N/A<br>N/A                             | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%   | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%   | -680.4%<br>-855.0%<br>651.2%<br>-669.2%  |
| Adjusted EBITDA  Set income margin  Growth Rate Analysis Y/Y  Sotal revenue  Sotal cost of revenues  See search and development expenses, net  See search and administrative expenses  | -2708.5%<br>-3115.6%<br>N/A<br>N/A<br>N/A                      | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%<br>13.4%                                      | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%<br>-1.9%                                    | -680.4%<br>-855.0%<br>651.2%<br>-669.2%<br>10.2%                                   |
| Adjusted EBITDA  Net income margin  Growth Rate Analysis Y/Y  Total revenue  Total cost of revenues  Research and development expenses, net  General and administrative expenses  Departing income   | -2708.5%<br>-3115.6%<br>N/A<br>N/A<br>N/A<br>N/A<br>N/A        | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%<br>13.4%<br>53.6%<br>-25.3%                   | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%<br>-1.9%<br>-25.5%<br>9.3%                  | -680.4%<br>-855.0%<br>651.2%<br>-669.2%<br>10.2%<br>-2.9%<br>2.5%                  |
| Adjusted EBITDA  Net income margin  Growth Rate Analysis Y/Y  Total revenue  Total cost of revenues  Research and development expenses, net  General and administrative expenses  Departing income  RESIDA   | -2708.5%<br>-3115.6%<br>N/A<br>N/A<br>N/A<br>N/A<br>N/A        | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%<br>13.4%<br>53.6%<br>-25.3%<br>-22.5%         | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%<br>-1.9%<br>-25.5%<br>9.3%<br>10.6%         | -680.4%<br>-855.0%<br>651.2%<br>-669.2%<br>10.2%<br>-2.9%<br>2.5%<br>2.9%          |
| Adjusted EBITDA  Jet income margin  Growth Rate Analysis Y/Y  Total revenue  Total cost of revenues  Research and development expenses, net  General and administrative expenses  Departing income  BITDA  Adjusted EBITDA                                     | -2708.5%<br>-3115.6%<br>N/A<br>N/A<br>N/A<br>N/A<br>N/A<br>N/A | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%<br>13.4%<br>53.6%<br>-25.3%<br>-22.5%<br>9.3% | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%<br>-1.9%<br>-25.5%<br>9.3%<br>10.6%<br>4.8% | -680.4%<br>-855.0%<br>651.2%<br>-669.2%<br>10.2%<br>-2.9%<br>2.5%<br>2.9%<br>-1.2% |
| BITDA margin Adjusted EBITDA Net income margin  Growth Rate Analysis Y/Y Total revenue Total cost of revenues Research and development expenses, net General and administrative expenses Operating income BITDA Adjusted EBITDA Net income LPS - fully diluted | -2708.5%<br>-3115.6%<br>N/A<br>N/A<br>N/A<br>N/A<br>N/A        | -5302.6%<br>-7106.1%<br>-44.2%<br>45.0%<br>13.4%<br>53.6%<br>-25.3%<br>-22.5%         | -5050.4%<br>-6511.1%<br>0.0%<br>-18.2%<br>-1.9%<br>-25.5%<br>9.3%<br>10.6%         | -680.4%<br>-855.0%<br>651.2%<br>-669.2%<br>10.2%<br>-2.9%<br>2.5%<br>2.9%          |

Source: Company Reports, Stonegate Capital Partners estimates



#### **VALUATION**

Pluristem Therapeutics, Inc., has developed an off-the-shelf regenerative therapy that requires no tissue matching. It is placenta derived, has demonstrated great success in clinical trials to date, and can easily be produced in large quantities at the Company's FDA and EU approved manufacturing facility. The Company has three pre-marketing clinical trials expected to begin in 2016 – one for critical limb ischemia in Europe, one for critical limb ischemia in Japan, and one for ARS in the US via the Animal Rule (collaboration with NIAID), which applies in situations where humans cannot be used for testing. And the Company has several other programs progressing in its pipeline as well.

The two trials related to CLI utilizing PLX-PAD cells have both received approvals for expedited pathways to marketing, given the unmet medical needs of the condition, high mortality and amputation rates, and the sizable market. Costs for treating CLI in the US are estimated at around \$10 billion, and around \$12 billion + globally each year. Current options to avoid amputation include endovascular treatments (angioplasty, stents, laser and directional atherectomy) on an outpatient basis or even more involved surgical treatments involving hospitalization. We believe that this indication/approach to commercialization presently holds the most near-term promise for PSTI. Additionally, Pluristem does have a collaboration with the NIAID announced in February 2016, under which PLX-R18 will be tested in large animals as a medical counter measure for the treatment of the hematologic components of ARS; results of a pivotal trial following dosing evaluation could be submitted as a BLA under the Animal Rule regulatory pathway, also an expedited pathway to approval. We will be watching progression of that program closely, as success could ultimately lead to significant purchases for stockpiling by the US government.

Our 2016E projections are in-line with public information and based on historical operations as well as the upcoming clinical work that will require funding. Management has stated that the Company has approximately two years of liquidity based on its past 6-months burn rate. Pluristem had approximately \$38M in cash and short-term securities as last reported, no debt on its balance sheet, and minimal dilution potential outstanding.

We believe that an appropriate tool for analyzing the longer-term opportunity for PSTI is through a discounted cash flow analysis (2016 – 2025). Exhibit 6 presents a summary of the detailed analysis we performed based on certain assumptions for the Company's CLI program alone, providing sensitivity for discount rates and terminal growth rates. Management has stated that marketing approval for CLI could be given late 2018 or early 2019. Acceptance into the accelerated pathways of Europe and Japan, both leaders in regenerative medicine, is very promising and lends great credibility to the results to date. While there are several other programs in the pipeline, most are still in the earlier stages of the lengthy clinical trials process.

A simple top line model was created to show a theoretical scaling up of sales within the CLI market, based on a total population size of approximately 2M patients. We assumed that marketing to CLI patients begins in 2019, and the numbers ramp slowly, starting at 3% and reaching 25% by 2025. We incorporated an average price of \$20,000 per patient per year. We have assigned a probability of commercialization of 40% at this point, given the stage and rarity of this non-traditional yet accelerated pathway.

We have also made conservative assumptions on Pluristem's changes in working capital, depreciation and amortization, as well as capex going forward. We incorporated a tax rate of 25% beginning in 2019; as last reported, the Company had a tax shield in excess of approximately \$29M as a result of accumulated losses.

A mid-range discount rate of 25% has been included, which we feel is appropriate given the timing and the need for reimbursement approvals in the future. We have incorporated terminal values ranging from 0% - 4%. And as a result, given all of our conservative assumptions and only focusing on the CLI indication for now, our discounted cash flows analysis for the critical limb ischemia opportunity results in a range of valuation from \$5.51 - \$6.27, with a midpoint of approximately \$6. PSTI currently trades at \$1.33 per share.

Exhibit 6: Summary of Discounted Flow Analysis

|       | Terminal Growth Rates |       |        |        |        |        |        |  |
|-------|-----------------------|-------|--------|--------|--------|--------|--------|--|
|       |                       |       | 0%     | 1%     | 2%     | 3%     | 4%     |  |
| و     | 2                     | 23.0% | \$6.69 | \$6.89 | \$7.10 | \$7.34 | \$7.60 |  |
| Rafe  |                       | 24.0% | \$6.10 | \$6.27 | \$6.45 | \$6.65 | \$6.87 |  |
| 1     |                       | 25.0% | \$5.57 | \$5.72 | \$5.87 | \$6.05 | \$6.23 |  |
| Disco |                       | 26.0% | \$5.10 | \$5.23 | \$5.36 | \$5.51 | \$5.67 |  |
| Ē     | <b>1</b>              | 27.0% | \$4.68 | \$4.79 | \$4.90 | \$5.03 | \$5.17 |  |

Source: Company Reports, Stonegate Capital Partners, Capital IQ



## **CORPORATE TIMELINE**

**April 2016 -** Pluristem signs agreement with Japan-based TES Holdings Co. to license a cell therapy patent for a variety of ischemic conditions

**February 2016** - Company announces that the National Institute of Allergy and Infectious Diseases will initiate studies in large animals for Pluristem's PLX-R18 as treatment for ARS

**December 2015 -** The FDA grants orphan drug designation to PLX-PAD cells for treatment of severe preeclampsia

**August 2015 -** Japan's PMDA clears PLX-PAD for use in clinical trials in Japan

August 2015 - Pluristem announces meeting with European Adaptive Pathway Discussion Group regarding clinical development plan for PLX cells in critical limb ischemia patients

October 2014 - The Company announces the development of PLX-R18 using Pluristem's 3D technology platform

**January 2013** - The Company opens its manufacturing facility in Haifa, Israel

**2007** - Pluristem purchases of all the patents and technology for the 3D expansion of adherent cells from the Weizmann Institute of Science and Technion - Israel Institute of Technology

**2007** - Pluristem is approved for listing on the NASDAQ (NasdaqCM: PSTI)

**2005** - Current Chairman and CEO, Zami Aberman, joins the Company and changes the business strategy to a therapeutics company using the 3D expansion technology

**2003** - Pluristem is incorporated as Pluristem Life Systems, Inc.; the initial business focuses on the manufacture and sales of 3D cell expansion systems

**2001** - The Company is founded in 2001 based on proprietary 3D stem cell expansion systems developed at the Israeli Weizmann Institute of Science

## PLURISTEM THERAPEUTICS, INC. GOVERNANCE

**Zami Aberman, Chairman and CEO** - Zami Aberman joined Pluristem in September 2005 and redirected the Company's strategy toward cell therapy using the maternal section of the placenta, combined with Pluristem's unique 3D manufacturing technology, as the source of Pluristem's potential products. Over his 20 years in high tech, Mr. Aberman has held top-level positions for companies in Israel, the U.S., Europe, Japan and South Korea, operating in such fields as robotics, software, VOIP, network security and others. He holds a B.Sc. in Mechanical Engineering from Ben Gurion University.

Yaky Yanay, President and Chief Operating Officer - Yaky Yanay has been Pluristem's President and Chief Operating Officer since 2014. He joined Pluristem in 2006 as the Chief Financial Officer. In March 2013, he was appointed the Company's Executive Vice President. Prior to joining Pluristem, Mr. Yanay was the Chief Financial Officer of Elbit Vision Systems Ltd., a publicly traded company. Before joining Elbit, he was manager of audit groups of the technology sector at Ernst & Young Israel. Mr. Yanay holds a bachelor's degree in business administration and accounting and is a CPA in Israel.

Hillit Mannor Shachar. M.D., M.B.A. - Vice President of Business Development - Hillit Mannor Shachar has been with Pluristem since October 2013 as Vice President of Business Development. Prior to joining the Company, she worked and consulted in the areas of business development and corporate development at companies including West Pharmaceutical Services, Nektar Therapeutics, Orex Computer Radiography, Transpharma Medical, Apax Partners, and at Deloitte Israel. Dr. Shachar holds B.A. and M.D. degrees from Northwestern University, an M.B.A. from Kellogg Recanati Executive Program, and an M.S.F.S. from Georgetown University.

Esther Lukasiewicz-Hagai, M.D., Ph.D. – Vice President Clinical and Medical Affairs - Dr. Lukasiewicz-Hagai joined Pluristem from Teva Global R&D, where she was Director, Clinical Program Leader, leading global clinical development in multiple biosimilars and drugs. She was also previously with the Gertner Institute for Epidemiology and Health Policy Research. Dr. Lukasiewicz-Hagai holds a M.D. from Necker-Enfants Malades Paris V School of Medicine, and a Master of Methodology and Statistics in Clinical Research and a Masters in Medical Science in Biostatistics and Epidemiology from Paris XI, as well as a Ph.D. in Biostatistics from Bar-Ilan University.

Sagi Moran, Vice President Operations - Sagi Moran joined Pluristem in June 2014. Mr. Moran was formerly Chief Technology Officer for a medical device startup, AxonoGen Ltd. He also previously Chief Operating Officer for NovoXel Ltd. He also was responsible for establishing a medical division for Qualitest Group Ltd., Israel's largest engineering and testing services group for the medical industry. Prior to that, he was with Lumenis Ltd., in in global R&D and operations management. Mr. Moran holds a Master of Business Administration from Recanati Executive MBA program at Tel-Aviv University, and a bachelor's degree in Information Systems from Haifa University.

Erez Egozi, Vice President of Finance — Erez Egozi joined Pluristem in March 2015. Prior to joining the Company, he was with Verint Systems, Inc., a public company, where he served as Senior Director of Finance-worldwide finance controller of that company's communications and cyber intelligence solutions division. His background also includes working at Intel Corporation finance department in the manufacturing plants in Israel, and serving as an auditor in the high technology sector at Deloitte & Touche Tel Aviv. He holds a bachelor's degree in economics and accounting from Beer-Sheva University, M.A. degree in law from Bar-Ilan University, and he is a CPA.

#### **Board of Directors:**

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Yaky Yanay – President and COO

Isaac Braun – Director

Mark Germain - Director

Moria Kwiat - Director

Hava Klemperer Meretzki – Director

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# **CONTACT INFORMATION**

**Pluristem Therapeutics, Inc.**USA Investor Relations - Karine Kleinhaus

Phone: 914-512-4109 karinek@pluristem.com

Israel Investor Relations - Efrat Kaduri

Phone: 972-74-710-8721 efratk@pluristem.com

Investor Relations Stonegate Capital Partners 8201 Preston Road Suite 325 Dallas, Texas 75225 www.stonegateinc.com