

PLURISTEM LIFE SYSTEMS INC  
Form 10QSB/A  
November 19, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-QSB /A

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period  
ended **September 30, 2004**

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period  
from \_\_\_\_\_ to  
\_\_\_\_\_

Commission file  
number **001-31392**

PLURISTEM LIFE SYSTEMS, INC.

(Exact name of small business issuer as specified in its charter)

Nevada

98-0351734

(State or other jurisdiction of incorporation or  
organization)

(IRS Employer Identification No.)

MATAM Advanced Technology Park, Building No. 20, Haifa, Israel 31905

(Address of principal executive offices)

011-972-4-850-1080

(Issuer's telephone number)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Check whether the issuer has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 26,858,483 common shares issued and outstanding as of October 25, 2004

Transitional Small Business Disclosure Format (Check one): Yes  No

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Company in the Development Stage)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2004

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Company in the Development Stage)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2004

IN U.S. DOLLARS

INDEX

-

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PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED  
BALANCE  
SHEETS

In U.S. Dollars  
(except share data)

September  
30,  
2004  
(Unaudited)

ASSETS

CURRENT  
ASSETS:

Cash and cash equivalents	\$220,762
Prepaid expenses	68,692
Other accounts receivables	36,908

326,362

Total

current assets

LONG-TERM  
RESTRICTED  
LEASE DEPOSIT

21,188

28,005

SEVERANCE  
PAY  
FUND

221,275

PROPERTY  
AND  
EQUIPMENT,  
NET

322,172

DEFERRED  
ISSUANCE  
EXPENSES

\$919,002

Total

assets

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED  
BALANCE SHEETS

In U.S. Dollars (except  
share data)

-

September  
30,  
2004

(Unaudited)

LIABILITIES  
AND  
STOCKHOLDERS'  
EQUITY

CURRENT  
LIABILITIES:

	\$3,387
Short-term bank credit	
	100,000
Current maturities know-how licensors	
Trade payables	60,941
Accrued expenses	175,129
Other accounts payable	57,603
<u>Total</u>	397,060

current liabilities

LONG-TERM  
LIABILITIES

	171,758
Know-how licensors, net of current maturities	
	210,000
Liability in respect of warrants	
	34,350
Accrued severance pay	
	416,108

COMMITMENTS  
AND  
CONTINGENCIES

STOCKHOLDERS  
EQUITY

Share capital:	
	268
Common stock \$0.00001 par value:	
Authorized: 1,400,000,000 shares	
Issued and Outstanding: 26,858,483 shares	

Additional paid-in capital	2,963,888
	(2,858,322)
Deficit accumulated during the development stage	105,834
	\$919,002

-

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED  
STATEMENTS OF  
OPERATIONS

In U.S. Dollars (except  
share data)

-

Three months ended		Period from May 11, 2001 (inception) through
September 30, 2004	September 30, 2003	September 30, 2004
(Unaudited)		
\$ 261,335	\$243,294	\$ 1,618,767

Research and development costs	213,349	73,557	2,145,385
General and administrative expenses	-	-	246,470
In-process research and development write-off	474,684	316,851	4,010,622
Financial expenses (income), net	(167,610)	5,608	(1,152,300)
Net loss	\$ 307,074	\$322,459	\$2,858,322
Basic and diluted net loss per share	\$(0.011)	\$(0.015)	
Weighted average number			



of  
shares  
used

in  
computing  
basic  
and  
diluted  
net  
loss

26,858,483 21,984,474

per  
share:

-

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

STATEMENTS OF  
CHANGES IN  
STOCKHOLDERS'  
EQUITY  
(DEFICIENCY)

In U.S. Dollars  
(except shares  
data)

	Common Stock		Additional	Receipts	Deficit	Total
	Shares	Amount	paid-in	On	Accumulated	Stockholders'
			Capital	account	during the	Equity
				of shares	Development	(Deficiency)
					Stage	
Balance as of May	-	\$ -	\$ -	\$ -	\$ -	\$ -

11,  
2001  
(date  
of  
incorporation)

35,000,000	350	2,150	-	-	2,500
Issuance of common stock July 9, 2001					
35,000,000	350	2,150	-	-	2,500
Balance as of June 30, 2001					
-	-	-	-	(77,903)	(77,903)
Loss for the year ended June 30, 2002					
35,000,000	350	2,150	-	(77,903)	(75,403)
Balance as of June 30, 2002					
Issuance of common stock on October 14, 2002,					
14,133,000	141	83,450	-	-	83,591

net of Issuance costs of \$17,359	-	-	11,760	-	-	11,760
Forgiveness of debt	(27,300,000)	(273)	273	-	-	-
Stocks cancelled on March 19, 2003	-	-	-	933,464	-	933,464
Receipts on account of stock and warrants, net of  finders and legal fees of \$56,540	-	-	-	-	(462,995)	(462,995)
Loss for the year ended June 30, 2003						
Balance as of June 30, 2003	21,833,000	\$ 218	\$ 97,633	\$ 933,464	\$ (540,898)	\$ 490,417

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

STATEMENTS OF CHANGES IN  
STOCKHOLDERS' EQUITY

In U.S. Dollars  
(except shares  
data)

	Common Stock	Additional paid-in Capital	Deficit accumulated Receipts During the on development of stage shares	Total Shareholders' Equity
	Shares Amount	Capital	of stage shares	Equity
Balance as of July 1, 2003	21,318,000 \$ 318,000	\$ 97,633	\$ (540,898) 933,464	\$ 490,417
Issuance of common stock on July 16, 2003, net of issuance costs of \$70,110	725,483	1,235,752	(933,464)	302,295
	3,000,000	-	-	30

Issuance of common stock on January 20, 2004	- -	192,000	- -	192,000
Issuance of warrants on January 20, 2004 for finder fee	1,000,000	799,990	- -	800,000
Common stock granted to consultants on  February 11, 2004	- -	357,618	- -	- 357,618
Stock based compensation related to warrants granted to consultants on December 31, 2003				
Exercise of warrants on				

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April 19, 2004	300,000	224,997	-	-	225,000
Loss for the year ended June 30, 2004	-	-	-	(2,010,350)	(2,010,350)
Balance as of June 30, 2004	26,858,483	\$2,907,990	\$	-(2,551,248)	\$ 357,010

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

In U.S. Dollars  
(except shares data)

Common Stock		Additional paid-in capital	Receipts on account of shares	Deficit accumulated During the development stage	Total Shareholders' Equity
Shares	Amount				
26,858,483	\$268	\$2,907,990	\$ -	\$(2,551,248)	\$357,010
Balance as of July					

1,  
2004

Stock-based  
compensation  
related  
to  
warrants

-	-	55,898	-	-	55,898
---	---	--------	---	---	--------

granted  
to  
consultants  
on  
December  
31,  
2003

-	-	-	-	(307,074)	(307,074)
---	---	---	---	-----------	-----------

Loss  
for  
the  
period  
ended  
September  
30,  
2004

26,858,483	\$ 268	\$2,963,888	\$ -	\$(2,858,322)	\$105,834
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Balance  
as of  
September  
30,  
2004  
(unaudited)

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED  
STATEMENTS OF  
CASH FLOWS

In U.S. Dollars

	Three months ended		Period from May 11, 2001 (inception)  through September 30 2004
	September 30, 2004	2003	2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (307,074)	\$(322,459)	\$ (2,858,322)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,507	21,300	117,308
Impairment of know-how	-	-	264,807
Deferred issuance costs amortization	34,934	-	97,038
	17,148	-	1,174,766



Stock-based compensation to consultants	-	-	246,470
In-process research and development write-off	2,881	4,234	26,358
Know-how licensors - imputed interest	(21,576)	(1,247)	(28,072)
Increase in accounts receivable	26,968	-	(29,942)
Decrease (increase) in prepaid expenses	(51,934)	30,692	51,534
Increase (decrease) in trade payables	54,017	(36,737)	(193,877)
Increase (decrease) in other accounts payable and accrued expenses	-	-	3,450
Increase in accrued interest			

due to related parties	(229)	-	(1,205)
Linkage differences and interest of long-term restricted lease deposit	(210,000)	-	(1,289,970)
Change in fair value of warrants	(1,778)	-	6,345
Accrued severance pay, net	(449,136)	(304,217)	(2,413,312)
Net cash used in operating activities			

CASH  
FLOWS  
FROM  
INVESTING  
ACTIVITIES:

-	-	31,899	
Acquisition of Pluristem Ltd. (1)	(2,333)	(9,730)	(127,990)
Purchase of			

property and equipment	-	-	(1,176)
Investment in long-term restricted lease deposit	-	-	(100,000)
Purchase of Know-how	(2,333)	(9,730)	(197,267)
Net cash used in investing activities			

CASH  
FLOWS  
FROM  
FINANCING  
ACTIVITIES:

	-	302,295	613,416
Issuance of common stock, net of issuance costs	-	-	1,272,790
Issuance of warrants	-	-	933,464
Receipts on account of stocks	3,364	(26)	3,361

Short-term bank credit, net	-	-	78,195
Proceeds from notes and loan payable to related parties	-	-	(69,885)
Repayments of notes and loan payable to related parties	3,364	302,269	2,831,341
Net cash provided by financing activities	(448,105)	(11,678)	220,762
Increase (decrease) in cash and cash equivalents	668,867	507,337	-
Cash and cash equivalents at the beginning of the period			

	\$220,762	\$495,659	\$ 220,762
Cash and cash equivalents at the end of the period			

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

CONSOLIDATED  
STATEMENTS OF  
CASH FLOWS

In U.S. Dollars

			Period from May 11, 2001 (inception) through
	Three months ended		September 30,
	September 30,		
	2004	2003	2004

Non-cash  
investing and  
financing  
information:

Unpaid know-how	\$ -	\$ -	\$300,000
--------------------	------	------	-----------

Forgiveness of debt \$ - \$ - \$ 11,760

(1)  
Acquisition  
of Pluristem  
Ltd.

Estimated  
fair value of  
assets  
acquired and  
liabilities  
assumed at  
the  
acquisition  
date:

Working capital (excluding cash and cash equivalents)	\$(427,176)
Long-term restricted lease deposit	18,807
Property and equipment	130,000
In-process research and development write-off	246,470
	\$(31,899)

The accompanying notes are an integral part of the consolidated financial statements.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

NOTES TO  
CONSOLIDATED  
FINANCIAL STATEMENTS

In U.S. Dollars

NOTE 1:- GENERAL

a. Pluristem Life Systems Inc. (the Company"), a Nevada Corporation, was incorporated and commenced operations on May 11, 2001. The Company has a wholly owned subsidiary, Pluristem Ltd. (the "subsidiary") that was incorporated under the laws of Israel, and began its activity in January 2004.

b. The Company is devoting substantially all of its efforts towards conducting research and development of critical cell expansion services to cord blood banks. In the course of such activities, the Company and its subsidiary have sustained operating losses and expect such losses to continue in the foreseeable future. The Company and its subsidiary have not generated any revenues or product sales and have not achieved profitable operations or positive cash flows from operations. The Company's deficit accumulated during the development stage aggregated to approximately \$2,858,322 thousand through September 30, 2004. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis.

The Company plans to continue to finance its operations with a combination of stock issuance and private placements and in the longer term, revenues from product sales. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its planned products.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

c. The accompanying unaudited interim consolidated financial statements have been prepared as of September 30, 2004 and for the three months then ended, in accordance with United States generally accepted accounting principles relating to the preparation of financial statements for interim periods. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month period ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ended June 30, 2005.

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

NOTES TO  
CONSOLIDATED  
FINANCIAL STATEMENTS

In U.S. Dollars

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. The significant accounting policies applied in the annual consolidated financial statements of the Company as of June 30, 2004 are applied consistently in these consolidated financial statements.

These financial statements should be read in conjunction with the audited annual financial statements of the Company as of June 30, 2004 and their accompanying notes.

b. Accounting for stock-based compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees ("APB 25") and Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation ("FIN 44") in accounting for its employee stock option plans. Under APB 25, when the exercise price of the Company's stock options is less than the market price of the underlying stocks on the date of grant, compensation expense is recognized.

Pro forma information regarding the Company's net loss and net loss per stock as required by Financial Accounting Standards Board Statement No. 148 "Accounting for Stock Based Compensation - Transaction and Disclosure ("SFAS No. 148") that amended Financial Accounting Standards Board Statement No. 123 ("SFAS 123") has been determined as if the Company had accounted for its stock options under the fair value method prescribed by SFAS No. 123.

The fair value for options granted is amortized over their vesting period and estimated at the date of grant using a Black-Scholes options pricing model with the following weighted average assumptions:

Dividend yield      H%

Volatility            92%

Average risk-free interest rate    L.2%

Expected life (in years)    10

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)



(Previous Name - A. I. SOFTWARE INC.)

NOTES TO  
CONSOLIDATED  
FINANCIAL STATEMENTS

In U.S. Dollars

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

Pro forma information under SFAS No. 123, is as follows:

	Three months ended		Period from
	September 30,		May 11,
			2001
			(Inception)
			through
	2004	2003	September
			30
			2004
Net loss available to Common stock - as reported	\$K07,074	\$K22,459	\$ 1,858,322
Deduct - stock-based employee compensation - intrinsic value	-	-	-
	174,588	-	284,473
Add - stock based employee compensation - fair			

value

	\$L81,662	\$K22,459	\$K,142,792
Pro forma net loss			

Earning  
per  
stock:

	\$ (0.011)	\$ (0.015)
Basic and diluted net loss per stock as reported		

	\$ (0.018)	\$ (0.015)
Basic and diluted pro forma net loss per stock		

PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY

(A Development Stage Company)

(Previous Name - A. I. SOFTWARE INC.)

NOTES TO  
CONSOLIDATED  
FINANCIAL STATEMENTS

In U.S. Dollars

NOTE 3:- CHANGES IN SHARE CAPITAL

Warrants issued to consultants:

In the framework of the stock option plan, the Company issued on December 30, 2003, 500,000 warrants to a consultant, for carrying out investor relation's activities over a period of two years ending December 31, 2004. On July 2004, the Company's board of directors approved to modify the terms of those 500,000 options (of which 250,000 are with an exercise price of \$1 per stock and 250,000 with an exercise price of \$1.25 per stock) to provide for a cashless exercise of the options. The board of directors also resolved that the options' exercise price will be reduced to \$0.4 and that the options will be fully vested. In addition, it was resolved to grant the consultant additional 500,000 options with an exercise price of \$0.4 per stock, vested immediately and with a cashless exercise feature.

The Company accounted for its warrants to consultants under the fair value method in accordance of SFAS 123 and EITF 96-18 "Accounting for Equity Instruments that are Issued to other than Employees for Acquiring, or in Conjunction with selling Goods or Services". The fair value for these warrants was estimated using Black-Scholes option-pricing model with the following weighted-average assumptions: risk-free interest rates of 4.12%, expected dividend yield of 0%, expected volatility of 98%, and a weighted-average contractual life of the warrants of approximately 9.5 years. Compensation expenses of \$17,148 were recognized during the three month period ended September 30, 2004 in accordance with EITF 96-18 and additional \$38,750 were recorded as prepaid expenses.

Item 2. Management's Discussion and Analysis or Plan of Operation.

FORWARD LOOKING STATEMENTS

This quarterly report contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "Risk Factors", that may cause our company's or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are stated in United States Dollars (US\$) and are prepared in accordance with United States Generally Accepted Accounting Principles.

In this quarterly report, unless otherwise specified, all dollar amounts are expressed in United States dollars and all references to "common shares" refer to the common shares in our capital stock.

As used in this quarterly report, the terms "we", "us", "our", and "Pluristem" mean Pluristem Life Systems, Inc. and our wholly owned subsidiary, unless otherwise indicated.

## Corporate History

We were incorporated in the State of Nevada under the name A.I. Software, Inc. on May 11, 2001 and commencing July 2001, we were engaged in software development. Our initial business plan at the time of our incorporation was premised on the use of artificial intelligence in computer programming technology and in many areas of the computer, Internet, robotics, and games industries. On July 1, 2001 we entered into a software development agreement with Empire Group, a software development firm, to develop for us the software algorithm program for an artificial intelligence software called "Randomix." A demonstration version of Randomix was completed by Empire Group in May of 2002. The software allowed a user to find a domain name for the user substantially similar to the domain name sought. We expected that there would be substantial demand for the software because many domain names quickly became unavailable in the dotcom (".com") internet domain. However, with the proliferation of other domain suffixes, (".org", ".net", ".ca", etc.) the need for Randomix was greatly diminished.

We were not successful in fully implementing our initial business plan in regards to our Randomix software. As a result, during March and April of 2003, our Board of Directors conducted an in-depth analysis of our business plan and related future prospects for software development companies. To better protect stockholder interests and provide future appreciation, it was decided to concurrently pursue initiatives in the biotech industry as an extension to our business.

On May 5, 2003, we entered into a License Agreement with the Weizmann Institute of Science and the Technion-Israel Institute of Technology to acquire an exclusive license for an innovative stem cell expansion technology. This technology, if fully developed and commercialized, will offer novel solutions to make procedures like bone marrow transplants and other methods of cell therapy more accessible to patients suffering from leukemia, lymphoma, myeloma and a broad range of complicated diseases and disorders. Under this License Agreement, we agreed to pay \$400,000 cash over time and we will pay royalties on our future sales and product or rights distribution transactions.

To enable us to conduct further research and development of the exclusive license for the stem cell expansion technology we acquired from the Weizmann Institute of Science and the Technion-Israel Institute of Technology, on June 10, 2003 we purchased 100% of the issued and outstanding shares of a research and development company based in Israel called Pluristem, Ltd. Pluristem, Ltd. was incorporated under the law of Israel on January 22, 2003 and has the facilities and personnel to conduct research and development in the field of stem cell research. As consideration for the shares of Pluristem, Ltd., we paid to the shareholder of Pluristem, Ltd. cash in the amount of \$1,000 and provided Pluristem, Ltd. with a line of credit in the amount of \$500,000. Accordingly, Pluristem, Ltd. became our wholly-owned subsidiary as of June 10, 2003.

On June 25, 2003, we changed our name from "A.I. Software, Inc." to "Pluristem Life Systems, Inc." The name change was effected with the Nevada Secretary of State on June 25, 2003 and took effect with the Non-NASDAQ Over the Counter Bulletin Board at the opening of trading on June 30, 2003 under our new stock symbol "PLRS".

## Our Current Business

With the acquisition of Pluristem, Ltd., we aim to become a leader in expansion of stem cells outside of the human body. Stem cells are unspecialized cells that can renew themselves for long periods through cell division. Scientists have developed sufficient fundamental understanding to use stem cells for cell therapy and bone marrow transplants

for the potential treatment of a broad range of complicated diseases. Cell therapy is the use of living cells in the treatment of medical disorders. Cell therapy is still in its beginning stages of research and development and only a few potential products are already in clinical studies.

We plan to specialize initially in the expansion of stem cells found in umbilical cord blood, using the technology platform we acquired under the License Agreement with the Weizmann Institute of Science and the Technion-Israel Institute of Technology. We intend to improve this technology platform and develop it into a functional stem cell expansion system that will be used to produce expanded hematopoietic stem cells for use in bone marrow transplantation into patients. We have named this system the PluriX™ Bioreactor system.

#### Brief Introduction on Stem Cell Research and Cell Therapy

Since 1998, when embryonic human stem cells were first isolated, research on stem cells has received much public attention. Stem cells have two important characteristics that distinguish them from other types of cells. First, they are unspecialized cells that renew themselves for long periods through cell division. Second, under certain physiologic or experimental conditions, stem cells can be induced to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Scientists primarily work with two kinds of stem cells from animals and humans: embryonic stem cells and adult stem cells, which have different functions and characteristics. In some adult tissues, such as bone marrow, muscle, and brain, discrete populations of adult stem cells generate replacements for cells that are lost through normal wear and tear, injury, or disease.

Cell therapy is the use of living cells in the treatment of medical disorders. Stem cells, progenitors and differentiated functional cells of various tissues are evolving as potential treatment modality for life threatening diseases and major clinical indications lacking effective cures. Cell therapy is still in its beginning stages of research and development and only a few potential products are already in clinical studies.

Even though we have the capability to work with embryonic stem cells, we have chosen to concentrate our efforts on hematopoietic stem cells. Hematopoietic stem cells can be found in every adult's bone marrow, which is the spongy tissue found in the cavities of our bones. Hematopoietic stem cells are the precursors of the various types of blood cells in the human body. These cells include:

- White cells that fight infections and inflammations (leukocytes) and form the basis of the immune system (lymphocytes);
- Red cells that carry oxygen through our bodies (erythrocytes); and
- Platelets that help blood to clot.

Scientists have developed sufficient understanding to actually use hematopoietic stem cells for therapy, such as through the procedure of bone marrow transplant. Thus, this class of human stem cell holds the promise of being able to repair or replace cells or tissues that are damaged or destroyed by many of our most devastating diseases and disabilities. Furthermore, bone marrow transplants are ultimate treatments in many pathological disorders, including:

- Malignant blood system diseases, such as leukemia, lymphoma and myeloma,
- Diseases characterized by the lack of, or defective, production of bone marrow, such as aplastic anaemia,
- Severe combined immune deficiency,

- Non-hematopoietic malignancies (solid tumors), or bone marrow disorders, following chemotherapy and radiation, and
- Metabolic diseases or congenital hemoglobinopathies, such as thalassemia.

For stem cell transplants to succeed, the donated stem cells must repopulate and/or engraft the recipient's bone marrow, where they will provide a new source of essential blood and immune system cells. Within the hematopoietic cell system, only a special type of stem cells called pluripotent hematopoietic stem cells have extensive capacities to expand, differentiate and self-renew. Accordingly, pluripotent hematopoietic stem cells are exclusively required for repopulation and engraftment of donated stem cells following transplantation. In spite of the key role of pluripotent hematopoietic stem cells in maintaining the hematopoietic cell system, they appear in extremely low frequency in the bone marrow tissue. The current technology limitation on maintaining or expanding undifferentiated stem cells outside of human body is a major drawback to essential clinical applications of these cells. This current unavailability of technology to expand the number of stem cells outside of human body reflects the need for novel stem cell regulators. However, in spite of all the challenges involved in hematopoietic stem cell transplants, physicians are now trying, sometimes successfully, to assist in hematopoietic and immune system recovery following high-dose chemotherapy and/or radiation therapy treatment for malignant and non-malignant diseases such as leukemia and certain immune and genetic disorders.

#### Brief Introduction on Bone Marrow Transplants

Bone marrow transplantation is a relatively new medical procedure being used to treat diseases once thought incurable. Since its first successful use in 1968, bone marrow transplants have been used to treat patients diagnosed with leukemia, aplastic anaemia, lymphomas such as Hodgkin's disease, multiple myeloma, immune deficiency disorders and some solid tumors such as breast and ovarian cancer. The bone marrow transplant procedure generally involves three phases. In the first phase, lasting 5 to 14 days, the bone marrow recipient is prepared for the graft. Immunosuppressive and cytotoxic chemotherapy administered with or without irradiation are used to enable the recipient to accept the graft, to prevent graft rejection, and in cases of acute leukemia, to eliminate residual leukemia.

In the second phase, bone marrow is procured from a compatible donor and intravenously administered to the graft recipient.

The third phase is a period of waiting for the bone marrow to engraft and function normally in the recipient. During the time required for engraftment (approximately 2 to 4 weeks), the graft recipient is vulnerable to infection, bleeding, severe weight loss, rejection of the graft and graft-versus-host disease. Graft-versus-host disease occurs in approximately 50% of bone marrow transplant patients. If the marrow engrafts and the patient survives the immediate post-transplant period (first 3 to 6 weeks), the patient faces another set of complications, including graft-versus-host disease and interstitial pneumonia. Interstitial pneumonia occurs in 60% of bone marrow transplant patients, typically 4 to 6 weeks post transplant. The disease progresses rapidly and is fatal in approximately 50% of the cases. 50%-60% of patients survive where the bone marrow transplant is made during disease remission, and only 10%-25% survive in cases where the bone marrow transplant is done outside of remission. (Source: The Cost Effectiveness of BMT Therapy and Its Policy Implications, School of Public Health, UCLA).

There are several types of bone marrow transplants. They are distinguished according to the source of the stem cells. An autologous bone marrow transplant means the transplant stem cells come from the patient. An allogenic bone marrow transplant means the stem cells come from a donor. A syngeneic bone marrow transplant means the stem cells come from an identical twin.

Research and clinical work in the field of bone marrow transplants is presently limited due to:

- The average number of active pluripotent hematopoietic stem cells in any given bone marrow is extremely low, less than 0.5% of total cells;
- The difficulties of the human body to accept bone marrow transplants from donors, and the ensuing damaging reactions;
- The patient is quite prone to infections following radiation and/or chemotherapy treatments, and may have been infected even prior to the transplant;
- Sorting of healthy cells from cancerous cells has not proven 100% successful, meaning that the bone marrow transplant can end up replacing cancerous cells with more cancerous cells, in the case that the transplant stem cells are autologous;
- The great complications in storing and enriching these cells in the absence of *in vitro* differentiation;
- The absence of a large-scale and sustainable model that enables the testing of the ability of hematopoietic stem cells to renew the hematopoietic cell system; and
- There are some clinical situations where autologous bone marrow after tumor purging provides insufficient numbers of hematopoietic stem cells for the bone marrow transplant.

Transplantation experts believe that the ideal approach to a successful stem cell transplant is to use a large number of stem cells to maximize the probability of bone marrow repopulation and minimize the time needed for the return of normal numbers of hematopoietic and immune cells in the patient.

One of the major efforts in developing hematopoietic stem cell technologies has been to identify new and better sources for stem cells. The majority of transplantable hematopoietic stem cells in adults currently come primarily from peripheral blood or adult donor bone marrow. Another important and attainable source of transplantable and lasting hematopoietic stem cells is from umbilical cord blood. Such blood is drawn from the umbilical cord after birth, but before the discharge of the placenta, giving way to the following advantages:

- The standard procedure at birth is that umbilical cord blood is discarded with the placenta. No morbidity is involved, making this option free of ethical controversy.
- Collection of umbilical cord blood is simple and non-invasive both to the mother and the baby;
- Use of umbilical cord blood is already approved by the Federal Drug Administration and does not require further clinical testing;
- The hematopoietic stem cells drawn from umbilical cord blood can differentiate into primary hematopoietic precursors and create hematopoietic clones in cultures better than those hematopoietic stem cells taken from adult bone marrow;
- Umbilical cord blood has lower levels of contamination with common viral pathogens, such as Cytomegalovirus, and is more tolerant of alloantigens; and
- Umbilical cord blood hematopoietic stem cells have high tolerance levels, giving way to lower graft-versus-host diseases.

It is important to note that scientists have found no difference in the functionality of hematopoietic stem cells drawn from bone marrow, peripheral blood or umbilical cord blood. However, owing to the small volume of blood collected

from umbilical cords (typically less than 100 ml), use of umbilical cord blood has been limited to date to transplants in babies and children weighing under 45 kg. Moreover, there are no existing hematopoietic stem cell expansion technologies for umbilical cord blood that can increase to the best of our knowledge the number of hematopoietic stem cells without causing differentiation of the hematopoietic stem cells. Once the hematopoietic stem cells have differentiated, they cannot be transplanted into the patient. Therefore, the development of a system that will facilitate the proliferation of hematopoietic stem cells in an appropriate culture media or substrate could enable the use of such hematopoietic stem cells drawn from umbilical cord blood for transplanting in adults where insufficient hematopoietic stem cells are available.

In summary, transplants of hematopoietic stem cells derived from umbilical cord blood are a novel alternative to conventional bone marrow transplants and have several unique advantages, in spite of their present quantitative limitations. Umbilical cord blood lends itself to sorting and storing in cord blood banks and transplant clinics, leading to the ability to build data bases of expanded umbilical cord blood for national and worldwide access and use, making search of bone marrow transplant donors easily facilitated and making autologous bone marrow transplants in adults potentially feasible. We believe that the advantages in use of umbilical cord blood hematopoietic stem cells, combined with our platform technology have the potential to change the ways bone marrow transplants are conducted in the future.

#### Our Core Technology - the PluriX™ Bioreactor System

For decades, scientists have attempted to "grow" stem cells outside of human body in culture to increase the number of stem cells for transplantation. The challenge of this undertaking lies in overcoming stem cells' predisposition to differentiate. Adult hematopoietic stem cells tend to produce other cells with limited repopulating properties when grown in culture rather than to replicate and regenerate additional stem cells. Current stem cell expansion techniques are complicated by the diverse mix of differentiated cells generated in stem cell cultures. Existing scientific methods considered in increasing the number of stem cells include culturing the stem cells on two-dimensional stromal layers and growing in the presence of cytokines. To the best of our knowledge, none of these existing methods to grow stem cells outside of patients' bodies are able to prevent differentiation of stem cells while promoting their proliferation.

Through the License Agreement we entered with the Weizmann Institute of Science and the Technion-Israel Institute of Technology, we acquired an exclusive license for an innovative stem cell expansion technology. This technology, if fully developed and commercialized, will offer novel solutions to expand hematopoietic stem cells taken from umbilical cord blood. We intend to improve this technology and develop it into a functional stem cell expansion system that we can sell or license to other research laboratories, umbilical cord blood banks, or clinics in the future. We have named this system the PluriX™ Bioreactor system.

The PluriX™ Bioreactor system is a system of stromal cell cultures and substrates that create an artificial physiological environment in which hematopoietic stem cells can grow and reproduce outside of the human body. The system recreates the environment, which exists in human bones, in which stem cells reproduce in nature. The stem cells are "tricked" into growing and reproducing in the PluriX™ Bioreactor in the same way they would in living bone, and because the size and scale of the PluriX™ Bioreactor can be much bigger than a human bone, the stem cell growth can be greatly expanded. We expect that the three dimensional PluriX™ Bioreactor system has the potential to bring about the expansion of umbilical cord blood hematopoietic stem cells to proportions that will be enough for a number of adult transplants, without promoting differentiation.

We are designing and developing the PluriX™ Bioreactor system to perform controlled expansion of hematopoietic stem cells for bone marrow transplants. The general idea is to cause self-renewal of early stage stem cells and prevent them from differentiating through use of the PluriX™ Bioreactor system. The PluriX™ Bioreactor system creates an artificial physiological environment in which hematopoietic stem cells can grow and reproduce. This system is in direct contrast to standard teflon bags or culture flasks, which cannot promote hematopoietic stem cells self-renewal and prevent their differentiation. In the PluriX™ Bioreactor system, hematopoietic stem cells are influenced by contact with



the surrounding environment, made up of stromal cell cultures and substrates. Therefore, by keeping the hematopoietic stem cells in the closed environment of the PluriX™ Bioreactor system, the hematopoietic stem cells maintain their original form, which means that they can proliferate without differentiating.

We believe that the PluriX™ Bioreactor system, once fully developed, will enable the production of certain stem cells, such as umbilical cord blood hematopoietic stem cells, for which there might otherwise be insufficient quantities available for many transplants. Having access to a sufficient number of hematopoietic stem cells is essential to successful clinical outcomes. This is particularly the case with umbilical cord blood transplants. The limited quantities of available hematopoietic stem cells in umbilical cord blood and difficulties in expanding the starting volumes to therapeutic quantities have restricted the widespread practice of umbilical cord blood transplants. The PluriX™ Bioreactor system is designed to solve this dilemma by providing the capability to easily and cost-effectively expand umbilical cord blood hematopoietic stem cells to higher quantities for therapeutic treatments.

The PluriX™ Bioreactor system is comprised of several components, including (1) a reservoir, (2) gas mixture, (3) a gas filter, (4) an injection point, (5) a Plug Flow Bioreactor, (6) a flow monitor and a flow valve, (7) a separating container, (8) a container for medium exchange, (9) a peristaltic pump, (10) a sampling point, (11) a container for medium exchange and (12) an oxygen monitor. The PluriX™ Bioreactor system is designed to be operated with minimal operator activity by a medical or laboratory technician. Operation of the PluriX™ Bioreactor system is intended to be relatively simple, and therefore, a trained lab technician will be able to operate and monitor between 10 to 20 PluriX™ Bioreactor systems at any one time. In other words, one lab technician will operate 70 to 100 PluriX™ Bioreactor systems per year.

#### Primary Advantages of PluriX™ Bioreactor System

We believe our core technology, the PluriX™ Bioreactor system, once fully developed, will have the following advantages:

- Our PluriX™ Bioreactor system can be used to expand umbilical cord blood hematopoietic stem cells for use in adult transplants. With the assistance of our PluriX™ Bioreactor system, one portion of umbilical cord blood hematopoietic stem cells can be expanded to quantities enough for a number of transplants. This means that healthy autologous umbilical cord blood hematopoietic stem cells can be taken at the time of birth, expanded into mature hematopoietic stem cells and stored by a cell bank in the instance that it may be needed by that specific patient at a later date. This will eliminate the current practice of transplanting cancerous cells back into the patient.
- Our PluriX™ Bioreactor system can be used for allogenic expansion, i.e. to expand the hematopoietic stem cells from donors other than the patient himself. Allogenic stem cells can also be expanded for use as a transplant source for adults in the instances that enough stem cells are not attainable from a particular donor.
- Our PluriX™ Bioreactor system can also be used for autologous proliferation, i.e. to expand the hematopoietic stem cells taken from the transplant patients themselves. Contrary to any existing available technologies known to us, our PluriX™ Bioreactor system will allow the use of autologous bone marrow transplantation in the case that healthy cells are not clearly attainable from the patient.
- Our PluriX™ Bioreactor system can be used to produce a high number of hematopoietic stem cells, which will result in increased potential for faster, successful engraftment of stem cells in transplant patients.
- By making the option of expanding hematopoietic stem cells taken from transplant patients themselves available, we believe that costs related to donor searches for bone marrow transplants will be reduced significantly;

- We believe that our PluriX™ Bioreactor system will produce by-products that will speed up the recovery time of transplant patients, thereby reducing the number of hospitalization days needed.

Alongside our research process on the PluriX™ Bioreactor system, we have also identified characterization processes of new proteins that are important to the differentiation of stem cells, both within and without patients' bodies. We plan to continue in the cleaning and characterization of these proteins with the intention of making them into commercial products.

#### Markets for Our Product and Services

There are presently between 40,000 to 50,000 bone marrow transplants performed annually worldwide. Approximately 18,000 of these bone marrow transplants are performed in the United States and approximately 25,000 are performed in Europe. We have not taken steps to determine the number of bone marrow transplants performed elsewhere. Of the 40,000 to 50,000 bone marrow transplants performed, only 5,000 are performed on babies and children. Furthermore, most of these 40,000 to 50,000 bone marrow transplants are allogeneic transplants, requiring patients to locate donors with compatible hematopoietic stem cells. Based on the fact that only one in three patients actually finds a compatible donor, we estimate that the number of potential bone marrow transplants should exceed 150,000 annually. Based on these statistics, we believe that the existing methods of transplanting human bone marrow have not been perfected and are far from reaching an ideal level of success.

Presently, the standard bone marrow transplant procedure costs approximately \$170,000 per patient. This translates into approximately \$5 billion annually that patients and their medical insurers around the world are spending currently for this procedure alone. In addition, to manage the risk of incompatibility between donor and patient stem cells, a separation procedure of the stem cells is frequently also performed at a cost of \$70,000. We believe that 15% to 20%, or 15,000 to 20,000 of the patients require this stem cell separation procedure as well, adding a further \$700 million to the current spending on bone marrow transplants in the United States. Combining these figures with similar expenditures in Europe and Asia, we estimate the current worldwide spending on bone marrow transplants to exceed \$7 billion per year.

We estimate that there are hundreds of cord blood banks in the world, most of them located in the United States and Europe. In 2001, they collectively cryo-preserved (frozen) and stored cord blood from some 34,000 to 36,000 donors and they project that the annual rate of growth of cord blood preserved will be over 15%. Due to the increased use of umbilical cord blood hematopoietic stem cells in bone marrow transplants, we expect that the number of cord blood banks will also grow significantly around the world. We also expect that, in developed countries, in the near future, umbilical cord blood may be drawn at the time of every birth and stored for later use. We believe that the stem cell expansion technology that we will make available through our PluriX™ Bioreactor system, together with proper marketing efforts, will increase the number of umbilical cord blood donors for personal use, i.e., parents storing the umbilical cord blood for their children's future, by more than doubling the existing growth rate. This will also provide a full base of hematopoietic stem cells donor opportunities to patients throughout the world. We project that the global market for the provision of stem cell expansion services can reach approximately \$8 billion.

#### Intellectual Property

Our success will depend in part on our ability, and the ability of our licensors, to obtain patent protection for our technology and processes we acquired under the License Agreement with the Weizmann Institute of Science and the Technion-Israel Institute of Technology. Under the License Agreement we have exclusive rights to the technology covered by International Application Published Under the Patent Cooperation Treaty publication number WO 00/46349 entitled "Method and Apparatus for Maintenance and expansion of hematopoietic stem cells and/or Progenitor Cells". This patent was filed with the World Intellectual Property Organization under the Patent Cooperation Treaty (PCT) patent number WO-00/46349 on August 10, 2000 for our core technology of the PluriX™ Bioreactor system. Our issued patent presents claims to: (i) certain apparatus for cell culturing, including a bioreactor

suitable for culturing human hematopoietic stem cells or hematopoietic progenitors cells; (ii) three-dimensional stromal cells based bioreactor. A patent was issued in South Africa in October, 2002, and is due to expire in approximately 2020. Patents were approved in Australia and New Zealand in July 2003 and are due to expire in approximately 2020. In addition, we and our exclusive licensors will file applications for patents in the United States and equivalent applications in certain other countries claiming other aspects of our technology and processes, including a number of U.S. patent applications and corresponding applications in other countries relating to various components of the PluriX™ Bioreactor system.

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us, or our licensors, will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us or our licensors will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us or our licensors. Since patent applications in the United States are maintained in secrecy until patents issue, we also cannot be certain that others did not first file applications for inventions covered by our, and our licensors' pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We rely on the license granted by Weizmann Institute of Science and Technion-Israel Institute of Technology and others for the patent rights related to our core technology, the PluriX™ Bioreactor system. If we breach the License Agreement or otherwise fail to comply with the License Agreements, or if the License Agreement expires or is otherwise terminated, we may lose our rights in such patents, which would have a material adverse affect on our business, financial condition and results of operations.

We applied for a U.S. Trademark on the word "PluriX" on June 22, 2003. The application has been reviewed by the assigned examining attorney of the U.S. Patent and Trademark office. No objections were lodged, although additional information was requested. We submitted a response on February 17, 2004.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It has not been, but is now our intended policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements will provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also will commence to require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements will generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of Pluristem, Ltd.. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. We have not conducted freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such

companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and commercialization of our technology.

## Research and Development

### Foundational Research

For the last five years, our Chief Technology Officer, Dr. Shai Meretzki, has made the initial strides in the development of our core technology, the PluriX™ Bioreactor system. Research was performed by Dr. Meretzki and his team in the laboratory of Dr. Shosh Merchav at the Technion - Israel Institute of Technology's Rappaport Faculty of Medicine. Dr. Meretzki also worked in close collaboration with Professor Dov Zipori and Dr. Avinoam Kadouri, both from the Weizmann Institute of Science. Professor Zipori specializes in cultures and stromal cells and Dr. Kadouri specializes in the planning and creation of bioreactors. Special carriers were used in our research and development process. In addition, this foundational research was conducted in joint cooperation with the laboratory of SCID-NOD mice at the Weizmann Institute of Science and with Plumacher Laboratories in Rotterdam. To this end, Plumacher Laboratories allocated a research physician to the project for over two years. The technology resulting from this research is the subject of our License Agreement (see "Intellectual Property").

### Ongoing Research and Development Plan

For the next three to four years, we intend to continue developing our stem cell expansion technology based on the PluriX™ Bioreactor system, which will consist of four broad stages:

**3D Stroma Culture Optimization** - During this stage, we are collecting stroma cells from donor bone marrow and growing them within the PluriX™ 3-D culture. We intend to focus on optimizing the capacity of the PluriX™ system to support the growth and long-term maintenance of our high-density three dimensional stromal cells cultures.

**Stem-cells/Stromal cells Co-Culture Development & Optimization** - At this stage we intend to focus on the establishment of the PluriX™ Bioreactors containing high-density cell and pluripotent hematopoietic stem cells co-cultures; maintenance of common cells on high-density cell-coated carriers and testing of expanded stem cells outside a host body using mice without immune systems repopulating cells assay.

**Characterization & Protein Analysis** - At this stage we intend to focus on the analysis of activity in media conditioned by the high-density cell cultures in the PluriX™ Bioreactor systems; expansion standardization of pluripotent hematopoietic stem cells and hematopoietic progenitors in the PluriX™ Bioreactor system and comparison to expansion in standard stromal cell cultures and analysis of protein content expressed in PluriX™ cell cultures by two-dimensional electrophoresis.

**Regulatory Approval** - We intend to prepare and file with the Food and Drug Administration and other relevant health authorities an investigational new drug application to initiate human clinical trials designed to demonstrate the safety and efficacy of expanded stem cells from umbilical cord blood. All research and development activities will be carried out under the advice of a Food and Drug Administration advisor.

## Employees

We presently have eight employees in Research & Development and five employees in management through our wholly owned subsidiary, Pluristem, Ltd.

### Competition

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical, medical device, medical products, chemical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the prevention or treatment of certain diseases and health conditions that we have targeted for product development. There can be no assurance that developments by others will not render our technology obsolete or non-competitive, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse affect on our business, financial condition and results of operations.

Our competition will be determined in part by the potential indications for which our technology is developed and ultimately approved by regulatory authorities. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our potential corporate partners, can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, develop and implement production and marketing plans, obtain and maintain patent protection and secure adequate capital resources. We expect our technology, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

We believe we compete with the following larger and more established specialized biotechnology companies that are developing devices and products to be used for the prevention or treatment of certain diseases and health conditions that we have targeted for product development: Aastrom Biosciences, Inc., ViaCell Inc., Gamida-Cell Ltd., Large Scale Biology Corporation, Advanced Cell Technology, Inc., BioTransplant Inc., and CellGenix. However, to the best of our knowledge none of these companies have developed a platform that can support expansion of hematopoietic stem cells without promoting their differentiation.

### Government Regulations and Supervision

Once fully developed, we intend to market our expanded hematopoietic stem cell products to doctors and their patients in the United States and in Europe. Accordingly, we believe our research and development activities and the manufacturing and marketing of our technology are subject to the laws and regulations of governmental authorities in the United States and other countries in which our technology will be marketed. Specifically, in the United States, the Food and Drug Administration, among other agencies, regulates new product approvals to establish safety and efficacy of these products. Governments in other countries have similar requirements for testing and marketing.

### Regulatory Process in the United States

Regulatory approval of new biological products is a lengthy procedure leading from development of a new product through pre-clinical and clinical testing. This process takes a number of years and requires the expenditure of significant resources. There can be no assurance that our technology will ultimately receive regulatory approval.

We will be required to develop our expanded stem cell product into a GMP-compliant product to be sold for therapeutic applications. "GMP" is a standard set for pharmaceutical and bio-pharmaceutical production operations and facilities by the World Health Organization and other health regulatory authorities. Normally there is extreme caution in allowing matter to be transplanted into the human body, but the severity of the diseases our applications will treat may result in certain leniency from the Food and Drug Administration for terminally ill patients (see "Product Approval").

The Food and Drug Administration has developed requirements with respect to somatic cell therapy and gene cell therapy products and has issued documents concerning the regulation of cellular and tissue-based products. It requires regulatory approval for certain human cellular or tissue based products, including cells produced in the PluriX™ Bioreactor system, through a biologic license application.

In addition, the output of expanded human stem cells from our PluriX™ Bioreactor system is potentially subject to regulation as medical products under the Federal Food, Drug and Cosmetic Act, and as biological products under the Public Health Service Act. Different regulatory requirements may apply to our technology depending on how they are categorized by the Food and Drug Administration under these laws.

Furthermore, the Food and Drug Administration has published regulations which require registration of certain facilities, and is in the process of publishing regulations for the manufacture or manipulation of human cellular or tissue based products which may impact our future clinics.

Regardless of how our technology is regulated, the Federal Food, Drug, and Cosmetic Act and other Federal statutes and regulations govern or influence the research, testing, manufacture, safety, labelling, storage, record-keeping, approval, distribution, use, reporting, advertising and promotion of our future products. Non-compliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

#### Product Approval

We are currently only in the developmental stage of our technology, PluriX™ Bioreactor system and the expanded hematopoietic stem cell product and have not begun the process of seeking regulatory approval from the Food and Drug Administration. Once our PluriX™ Bioreactor system and the expanded hematopoietic stem cell product are fully developed, we intend to consult with consultants and the Food and Drug Administration to assist us in determining our path in the process toward gaining regulatory approval. Obtaining regulatory approval of new biological products from the Food and Drug Administration is a lengthy procedure leading from development of a new product through pre-clinical and clinical testing. This process takes a number of years and requires the expenditure of significant resources. There can be no assurance that our technology will ultimately receive regulatory approval. We summarize below our understanding of the regulatory approval requirements that may be applicable to us if we begin the process of seeking an approval from the Food and Drug Administration.

Generally, in order to obtain an approval from the Food and Drug Administration of a new medical product, an applicant must submit proof of safety and efficacy. In some cases, such proof entails extensive pre-clinical and clinical laboratory tests. The testing, preparation of necessary applications and processing of those applications by the Food and Drug Administration is expensive and may take several years to complete. There can be no assurance that the Food and Drug Administration will act favorably or in a timely manner in reviewing submitted applications, and an applicant may encounter significant difficulties or costs in its efforts to obtain Food and Drug Administration approvals, in turn, which could delay or preclude the applicant from marketing any products it may develop. The Food and Drug Administration may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be

withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which an applicant will have the exclusive right to exploit such technologies.

If human clinical trials of a proposed medical product are required, the manufacturer or distributor of the product will have to file an investigational new drug submission with the Food and Drug Administration prior to commencing human clinical trials. The submission must be supported by data, typically including the results of pre-clinical and laboratory testing. Following submission of the investigational device exemption or investigational new drug, the Food and Drug Administration has 30 days to review the application and raise safety and other clinical trial issues. If an applicant is not notified of objections within that period, clinical trials may be initiated, and human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the Food and Drug Administration.

The product that we will develop, expanded hematopoietic stem cell product will be subject to the requirements of clinical testing to demonstrate safety and effectiveness and the approval of the Food and Drug Administration prior to marketing and distribution.

In addition, we, and any contract manufacturer, will be required to be registered as a biologic product manufacturer with the Food and Drug Administration as part of the product approval process. The Food and Drug Administration will inspect us on a routine basis for compliance with the Food and Drug Administration's Quality System Regulations. The regulations of the Food and Drug Administration would require that we, and any contract manufacturer, design, manufacture and service products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. The Food and Drug Administration prohibits a company from promoting an approved product for unapproved applications and reviews company labelling for accuracy.

Therefore, our expanded hematopoietic stem cell product will be regulated by the Food and Drug Administration as a licensed biologic, although there can be no assurance that the Food and Drug Administration will not choose to regulate these stem cells in a different manner. The Food and Drug Administration categorizes human cell or tissue based products as either minimally manipulated or more than minimally manipulated, and has proposed that more than minimally manipulated products be regulated through a "tiered approach intended to regulate human cellular and tissue based products only to the extent necessary to protect public health." For products which may be regulated as biologics, the Food and Drug Administration requires: (i) preclinical laboratory and animal testing; (ii) submission to the Food and Drug Administration of an investigational new drug exemption which must be effective prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the Food and Drug Administration of a biologic license application; and (v) review and approval of the biologic license application as well as inspections of the manufacturing facility by the Food and Drug Administration prior to commercial marketing of the product.

Generally, pre-clinical testing covers laboratory evaluation of product chemistry and formulation as well as animal studies to assess the safety and efficacy of the product. The results of these tests are submitted to the Food and Drug Administration as part of the investigational new drug exemption. Following the submission of an investigational new drug exemption, the Food and Drug Administration has 30 days to review the application and raise safety and other clinical trial issues. If an applicant is not notified of objections within that period, clinical trials may be initiated. Clinical trials are typically conducted in three sequential phases. Phase I represents the initial administration of the drug or biologic to a small group of humans, either healthy volunteers or patients, to test for safety and other relevant factors. Phase II involves studies in a small number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range and to gather additional data relating to safety and potential adverse affects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, multi-center Phase III studies are initiated to establish safety and efficacy in an expanded patient population and multiple clinical study sites. The Food and Drug Administration reviews both the clinical plans and the

results of the trials and may request an applicant to discontinue the trials at any time if there are significant safety issues.

The results of the pre-clinical tests and clinical trials are submitted to the Food and Drug Administration in the form of a biologic license application for marketing approval. The testing and approval process is likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Additional animal studies or clinical trials may be requested during the Food and Drug Administration review period that may delay marketing approval. After the Food and Drug Administration approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The Food and Drug Administration requires that adverse effects be reported to the Food and Drug Administration and may also require post-marketing testing and surveillance to monitor for adverse effects, which can involve significant expense.

Under current requirements, facilities manufacturing biological products must also be licensed. To accomplish this, a biologic license application must be filed with the Food and Drug Administration. The biologic license application describes the facilities, equipment and personnel involved in the manufacturing process. An establishment license is granted on the basis of inspections of the applicant's facilities in which the primary focus is on compliance with regulations and procedures and the ability to consistently manufacture the product in the facility in accordance with the investigational new drug exemption. If the Food and Drug Administration finds the inspection unsatisfactory, it may decline to approve the biologic license application, resulting in a delay in production of products.

As part of the approval process for human biological products, each manufacturing facility must be registered and inspected by the Food and Drug Administration prior to marketing approval. In addition, state agency inspections and approvals may also be required for a biological product to be shipped out of state.

#### Regulatory Process in Europe

If we successfully develop our expanded hematopoietic stem cell product and seek regulatory approval in Europe, we believe our expanded hematopoietic stem cell product may be regulated in Europe as a biological product, under the authority of the European Medicinal Evaluation Authority (EMA) being implemented by European Union member countries. The application process for approval of our product will be similar to that undergone in the United States.

#### Plan of Operations

Our primary objective over the twelve months ending September 30, 2005 will be to further develop the expanded hematopoietic stem cell product and process. We will perform the development of the production process performed in the PluriX Bioreactor. Methods for the preparation of the cord blood seed, its freezing and thawing, development of the stromal cells and establishment of a master cell bank and working cell bank will be developed first. Following bioprocess development, fill and finish and development of analytical methods will be performed. In parallel, we will set up a quality assurance plan and implement it. A documentation center and compliance procedures will be established. In parallel, we will execute pre-clinical studies to demonstrate the expanded hematopoietic stem cell product activity in repopulating mice bone marrow. Regulatory activities will start by crystallizing the regulatory strategy, preparing a pre-filing document and perform a pre-filing meeting with the Food and Drug Administration.

Concurrently, we will initiate contact with research centers and cord blood banks to establish cooperative relations for future business development.

We will continue our cooperation with the Technion Institute of Technology in Israel regarding the Magneton grant received from the Israeli government. Within this grant we, together with the Technion researchers will further develop the PluriX™ bioreactor using biodegradable scaffold structure which imitates the human bone.



We intend to consult with an Food and Drug Administration consultants to assist us in determining the process toward gaining Food and Drug Administration regulatory approval.

We have not generated any revenues and our operating activities have used cash resources of over \$449,136 for the three month period ended September 30, 2004. This negative cash flow is attributable to our operation expenses, including but not limited to, research and development expense and the payment of our audit fees and legal fees. We anticipate that our operating expenses will increase as we intend to conduct detailed development of our first product - expanded hematopoietic stem cell product, animal pre-clinical trials and experiments and clinical trials and work towards its completion. We estimate our expenses in the twelve months ending September 30, 2005 will be approximately \$2,100,000, generally falling in two major categories: research and development costs and general and administrative expenses.

#### Research and Development Costs

For the twelve months ending September 30, 2005, we estimate that our research and development costs will be approximately \$1,400,000. We intend to spend our research and development costs on optimizing the 3-D bioreactor operations, developing the expanded hematopoietic stem cell product, implanting stem cells from cord blood into the stromal cell cultures of PluriX™ bioreactors for expansion and on conducting studies on mice to examine stem cell development and expansion.

#### General and Administrative Expenses

For the twelve months ending September 30, 2005, we estimate that our general and administrative expenses will be approximately \$700,000. These expenses will include office and miscellaneous charges, which consist primarily of charges incurred for purchase of office supplies and other administrative expenses. These expenses will also include professional fees, which consist primarily of accounting and auditing fees for the year-end audit and legal fees for securities advice, directors liability insurance and cost of fundraising.

We do not expect to generate any revenues in the twelve month period ending September 30, 2005. Our products will not be ready for sale for up to five years.

In our management's opinion, we need to achieve the following events or milestones in the next twelve months in order for us to begin generating revenues as planned within five years:

- Raise equity or debt financing or a combination of equity and debt financing of at least \$12,000,000.
- Build new bioreactor prototypes for continued research and for testing its functionality in production operation conditions.
- Optimize 3-D PluriX™ bioreactor operations - Using the 3-D environment of the PluriX™, a dense population of stromal cells (support cells) has been reached to provide the basis for stem cell expansion without differentiation. The stromal cells release a signal to prevent differentiation. Optimization of the bioreactor system is a continuous process to enable the stem cells to self-renew while remaining in their original state.
- Development of expanded hematopoietic stem cell product process and analytical methods.
- Studies to obtain an animal model. Trials will be conducted on SCID mice to examine the stem cell development and expansion process. "SCID mice" are mice without immune systems so that they can be used to simulate human immune systems.
- Crystallize the regulatory and medical strategy prior to meeting with the Food and Drug Administration.

- Prepare a pre-filing document and attend pre-filing meeting with the Food and Drug Administration.
- Establish relations with research centres and cord blood banks.

#### Research and Development

During the twelve month period ended June 30, 2004 and during the three month period ended September 30, 2004, we set up and began research activities in our clean rooms and laboratory. We built bioreactors to conduct research and development in a 3-D environment and seeded stromal cells into the bioreactors to produce the stromal cell culture where the stem cells will be implanted. Throughout this period and into 2005, we will continue with the R&D activities referenced above.

#### Purchase or Sale of Equipment

With the acquisition of Pluristem Ltd., we obtained much of the specialized laboratory equipment that we need to conduct our research. This equipment included incubators, freezers, computers, hot plates, generators, microscopes, and other equipment. We expect that we now own most of the laboratory equipment that we will need to conduct our planned research and development for the twelve month period ended September 30, 2005.

#### Going Concern

Due to our being a development stage company and not having generated revenues, in the consolidated financial statements for the year ended June 30, 2004, we included an explanatory paragraph regarding concerns about our ability to continue as a going concern. Our consolidated financial statements contain additional note disclosures describing the circumstances that lead to this disclosure.

The continuation of our business is dependent upon us raising additional financial support. The issuance of additional equity securities by us could result in a significant dilution in the equity interests of our current stockholders. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments.

#### APPLICATION OF CRITICAL ACCOUNTING POLICIES

Our financial statements and accompanying notes are prepared in accordance with generally accepted accounting principles in the United States. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our consolidated financial statements is critical to an understanding of our financials.

#### Acquisition of technology rights

In the acquisition of stem cell expansion technology rights through the License Agreement, we considered whether these rights meet the criteria of an asset or should be expensed. As a result of the negative cash flows that have occurred and are expected to continue in the foreseeable future, the PluriX™ Bio-reactor System and License Agreement technology assets which we acquired in the 2003 fiscal year were written off during the 2004 fiscal year.

#### Going Concern

Our annual financial statements have been prepared on the going concern basis, which assumes the realization of assets and liquidation of liabilities in the normal course of operations. The financial statements have been prepared

assuming we will continue as a going concern. However, certain conditions exist which raise doubt about our ability to continue as a going concern. We have suffered recurring losses from operations and have accumulated losses of approximately \$2,551,248 since inception through the year ended June 30, 2004 and an additional \$307,074 through the three month period ending September 30, 2004.

#### Off Balance Sheet Arrangements

Our company has no off balance sheet arrangements that are not disclosed in our Annual Report on Form 10-KSB as filed with the Securities and Exchange Commission on September 28, 2004.

#### RISK FACTORS

We have not earned any revenues since our incorporation and only have a limited operating history in our current business of developing and commercializing stem cell expansion technology, which raise doubt about our ability to continue as a going concern.

Our company has a limited operating history in our current business of developing and commercializing stem cell expansion technology and must be considered in the development stage. We were incorporated on May 11, 2001 with a business plan to develop an artificial intelligence software called Randomix. We were not successful in implementing our original business plan in regard to our Randomix software and as a result we decided in April of 2003 to pursue initiatives in the biotechnology industry as an extension to our business. In May of 2003 we entered into a license agreement with the Weizmann Institute of Science and the Technion-Israel Institute of Technology to acquire an exclusive license for a stem cell expansion technology. In June of 2003, we acquired our wholly-owned subsidiary, Pluristem, Ltd., based in Israel to conduct further research and development of the exclusive stem cell expansion technology licensed to us.

We have not generated any revenues since our inception and we will, in all likelihood, continue to incur operating expenses without significant revenues until we successfully develop and commercialise our stem cell expansion technology. Our primary source of funds has been the sale of our common stock. We cannot assure that we will be able to generate any significant revenues or income. These circumstances make us dependent on additional financial support until profitability is achieved. There is no assurance that we will ever be profitable, and we had a going concern note as described in an explanatory paragraph to our consolidated financial statements for the year ended June 30, 2004.

Our likelihood of profit depends on our ability to develop and commercialize our stem cell expansion technology, which is currently in the development stage. If we are unable to complete the development and commercialization of our stem cell expansion technology successfully, our likelihood of profit will be limited severely.

We are engaged in the business of developing and commercializing a technology called the PluriX™ Bioreactor system and a product called expanded hematopoietic stem cells. The proposed function of our PluriX™ Bioreactor system is to allow researchers and physicians to expand hematopoietic stem cells outside of the human body without differentiation so they may use in bone marrow transplants and other methods of cell therapy. Our PluriX™ Bioreactor system and expanded hematopoietic stem cell product are in the development stage and we have not begun the regulatory approval process for our PluriX™ Bioreactor system. We have not realized a profit from our operations to date and there is little likelihood that we will realize any profits in the short or medium term. Any profitability in the future from our business will be dependent upon successful commercialization of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, which will require significant additional research and development as well as substantial clinical trials.

If we encounter problems or delays in the research and development of our PluriX™ Bioreactor system and/or expanded hematopoietic stem cell product, we may not be able to raise sufficient capital to finance our operation during the

period required to resolve the problems or delays.

Our PluriX™ Bioreactor system and expanded hematopoietic stem cell product are currently in the development stage and we anticipate that we will continue to incur operating expenses without significant revenues until we have successfully completed all necessary research and clinical trials. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technology. Our research and development programs may not be successful, and our cell culture technology may not facilitate the production of cells outside the human body with the expected result. Our PluriX™ Bioreactor system may not prove to be safe and efficacious in clinical trials. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue. Accordingly, we may be forced to discontinue or suspend our operations.

We need to raise additional financing to support the research and development of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product in the future but we cannot be sure we will be able to obtain additional financing on terms favourable to us when needed. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.

We raised net proceeds of \$1,235,759 in a private placement of our securities which closed in July of 2003 and net proceeds of \$1,272,790 in another private placement of our securities which closed in January of 2004 to support the development and commercialization of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product. These funds were being expended to fund operations until November, 2004. Our ability to continue to develop and commercialise the PluriX™ Bioreactor system and expanded hematopoietic stem cell product is dependent upon our ability to raise significant additional financing immediately and otherwise when needed. If we are unable to obtain such financing, we will not be able to fully develop and commercialise our technology. Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- the effect of commercialization activities and facility expansions if and as required.

We have limited financial resources and to date, no cash flow from operations and we are dependent for funds on our ability to sell our common stock, primarily on a private placement basis. There can be no assurance that we will be able to obtain financing on that basis in light of factors such as the market demand for our securities, the state of financial markets generally and other relevant factors. Any sale of our common stock in the future will result in dilution to existing shareholders. Furthermore, there is no assurance that we will not incur debt in the future, that we will have sufficient funds to repay our future indebtedness or that we will not default on our future debts, jeopardizing our business viability. Finally, we may not be able to borrow or raise additional capital in the future to meet our needs or to otherwise provide the capital necessary to conduct the development and commercialization of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, which might result in the loss of some or all of your investment in our common stock.

If we fail to obtain and maintain required regulatory approvals for our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, our ability to commercialize our PluriX™ Bioreactor system and sell our hematopoietic stem cell product will be limited severely.

Once fully developed, we intend to market our PluriX™ Bioreactor system and expanded hematopoietic stem cell product primarily in the United States, Europe and Japan. We must obtain the approval of the Food and Drug Administration before commercialization of our technology may commence in the United States and approval of

similar agencies in Europe before we may commence commercialization in Europe. We may also be required to obtain additional approvals from foreign regulatory authorities to commence our marketing activities in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product or of the cells produced in the PluriX™ Bioreactor system, including long-term sustained cell engraftment, or if one or more patients die or suffer severe complications in future clinical trials, the Food and Drug Administration or other regulatory authorities could delay or withhold regulatory approval of our technology.

Furthermore, even if we obtain regulatory approval for our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the Food and Drug Administration, other regulatory agencies, and governments in other countries will continue to review and inspect marketed products, manufacturers and manufacturing facilities. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, governmental regulatory agencies may establish additional regulations which could prevent or delay regulatory approval of our technology.

Even if we obtain regulatory approvals to commercialize our technology, we may encounter a lack of commercial acceptance of our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, which would impair the profitability of our business.

Our research and development efforts are primarily directed toward obtaining regulatory approval to market the PluriX™ Bioreactor system and expanded hematopoietic stem cell product as an alternative to, or as an improvement for, the traditional bone marrow harvest and peripheral blood progenitor cell stem cell collection methods. These stem cell collection methods have been widely practiced for a number of years, and our technology may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, our PluriX™ Bioreactor system and expanded hematopoietic stem cell product may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technology and our potential revenues. As a result, even if we obtain all required regulatory approvals, we cannot be certain that our PluriX™ Bioreactor system and expanded hematopoietic stem cell product will be adopted at a level that would allow us to operate profitably.

If we do not keep pace with our competitors and with technological and market changes, our technology may become obsolete and our business may suffer.

The market for our technology is very competitive, is subject to rapid technological changes and varies for different individual products. We believe that there are potentially many competitive approaches being pursued in competition to our technology, including some by private companies for which information is difficult to obtain.

Many of our competitors have significantly greater resources, more product candidates and have developed product candidates and processes that directly compete with our technology. Our competitors may have developed, or could in the future develop, new technologies that compete with our technology or even render our technology obsolete. Our technology is designed to expand hematopoietic stem cells outside of the human body without differentiation so they may be used in bone marrow transplants and other methods of cell therapy. Even if we are able to demonstrate improved or equivalent results, researchers and practitioners may not use our technology and we will suffer a competitive disadvantage. Finally, to the extent that others develop new technologies that address the targeted application for our PluriX™ Bioreactor system and expanded hematopoietic stem cell product, our business will suffer.

We depend to a significant extent on certain key personnel, the loss of any of whom may materially and adversely affect our company.

Our success depends on a significant extent to the continued services of certain highly qualified scientific and management personnel, including our Chief Technology Officer, Dr. Shai Meretzki. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. We do not maintain key person insurance on the lives of any of our officers or employees.

Our success depends in large part on our ability to develop and protect our PluriX™ Bioreactor system technology. If our patents and proprietary right agreements do not provide sufficient protection for our PluriX™ Bioreactor system technology, our business and competitive position will suffer.

We rely on an exclusive, world-wide license relating to the production of human cells granted to us by the Weizmann Institute of Science and Technion-Israel Institute of Technology for certain of our patent rights. If we materially breach such agreement or otherwise fail to materially comply with such agreement, or if such agreement expires or is otherwise terminated by us, we may lose our rights under the patents held by the Weizmann Institute of Science and Technion-Israel Institute of Technology. At the latest, the license will terminate when the patents underlying the license expire. The underlying patents will expire in approximately 2020. Also, the scope of the patents licensed to us may not be sufficiently broad to offer meaningful protection. In addition, the patents licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Significantly, we do not as yet have patents in the United States or Europe or any other major market, although patents have been applied for.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

We may be subject to intellectual property litigation such as patent infringement claims, which could adversely affect our business.

Our success will also depend in part on our ability to develop commercially viable technology without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to develop and market our PluriX™ Bioreactor system in the future. In the event of an intellectual property dispute, we may be forced to litigate. Intellectual property litigation would divert management's attention from developing our technology and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and commercialization of our PluriX™ Bioreactor system.

Potential product liability claims could adversely affect our future earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of the PluriX™ Bioreactor system and expanded hematopoietic stem cell product during research and development efforts, including future clinical trials, or after commercialization results in adverse affects. As a result, we may incur significant product liability exposure. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

Our principal research and development facilities are located in Israel and the unstable military and political conditions of Israel may cause interruption or suspension of our business operations without warning.

Our principal research and development facilities are located in Israel. As a result, we are directly influenced by the political, economic and military conditions affecting Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and, since September 2000, involving the Palestinian population, and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel and companies based in Israel. Acts of random terrorism periodically occur which could affect our operations or personnel.

In addition, Israeli-based companies and companies doing business with Israel, have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel's establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner these problems will be resolved. Also, since the end of September 2000, there has been a marked increase in the level of terrorism in Israel, which has significantly damaged both the Israeli economy and levels of foreign and local investment.

Furthermore, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. All Israeli male citizens who have served in the army are subject to an obligation to perform reserve duty until they are between 45 and 54 years old, depending upon the nature of their military service.

Because some of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against the management for misconduct and may not be able to enforce judgement and civil liabilities against our officers, directors, experts and agents.

Most of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state.

Because we do not intend to pay any dividends on our common stock, investors seeking dividend income or liquidity should not purchase shares of our common stock.

We have not declared or paid any dividends on our common stock since our inception, and we do not anticipate paying any such dividends for the foreseeable future. Investors seeking dividend income or liquidity should not invest in our common stock.

### Item 3. Controls and Procedures.

As required by Rule 13a-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of the design and operation of our company's disclosure controls and procedures as of the end of the period covered by this quarterly report, being September 30, 2004. This evaluation was carried out under the supervision and with the participation of our company's management, including our company's president and chief executive officer. Based upon that evaluation, our company's president and chief executive officer concluded that our company's disclosure controls and procedures are effective as at the end of the period covered by this report. There have been no significant changes in our company's internal controls or in other factors, which could significantly affect internal controls subsequent to the date we carried out our evaluation.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that

information required to be disclosed in our company's reports filed under the Exchange Act is accumulated and communicated to management, including our company's president and chief executive officer as appropriate, to allow timely decisions regarding required disclosure.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

We know of no material, active or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceedings or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder are an adverse party or has a material interest adverse to us.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Submission of Matters to a Vote of Security Holders.

None.

### Item 5. Other Information.

On August 10, 2004 our Board of Directors appointed Dr. Menachem (Mendi) Ze'evi as a director of our company.

On October 17, 2004 Dr. Menachem (Mendi) Ze'evi resigned as our Chief Executive Officer and we appointed Dr. Shai Meretzki as our acting Chief Executive Officer.

### Item 6. Exhibits.

Exhibits required by Item 601 of Regulation S-B

Exhibit Number	Description
(3)	(i) Articles of Incorporation; and (ii) Bylaws
3.1	Articles of Incorporation (incorporated by reference from our Registration Statement on Form SB-2 filed September 10, 2001).
3.2	Bylaws (incorporated by reference from our Registration Statement on Form SB-2 filed September 10, 2001).
3.3	Restated Bylaws (incorporated by reference from our Quarterly Report on Form 10-QSB filed November 19, 2003).
(10)	Material Contracts
10.1	Software Development Agreement (incorporated by reference from our Registration Statement on Form SB-2 filed September 10, 2001).
10.2	Exclusive, World Wide Patent and Technology License and Assignment Agreement (incorporated by reference from our Current Report on Form 8-K filed May 6, 2003).
10.3	



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- Form of Subscription Agreement between our company and those investors listed who participated in the private placement which closed on July 16, 2003 (incorporated by reference from our Registration Statement on Form SB-2 filed February 27, 2004).
- 10.4 Form of Registration Rights Agreement between our company and those investors listed who participated in the private placement which closed on January 15, 2004 (incorporated by reference from our Registration Statement on Form SB-2 filed February 27, 2004).
- 10.5 Form of Registration Rights Agreement between our company and those investors listed who participated in the private placement which closed on January 15, 2004 (incorporated by reference from our Registration Statement on Form SB-2 filed February 27, 2004).
- 10.6 Form of Investors Relations Agreements between our company and those individuals carrying out investor relations activities dated January 28, 2004 (incorporated by reference from our Registration Statement on Form SB-2 filed February 27, 2004).
- 10.7 Consulting Agreement between Pluristem Life Systems, Inc. and Yokim Asset Management Corp. dated March 26, 2004. (Incorporated by reference from our Quarterly Report on Form 10-QSB filed May 25, 2004).
- 10.8 Employment Agreement between Pluristem Ltd. and Yossi Keret dated May 29, 2004. (Incorporated by reference from our Annual Report on Form 10-KSB filed September 28, 2004).
- (14) Code of Ethics
- 14.1\* Code of Business Conduct and Ethics and Compliance Program adopted by the Board of Directors
- (21) Subsidiaries of the small business issuer  
Pluristem, Ltd.
- (31) Rule 13a-14(a)/15d-14(a) Certifications
- 31.1\* Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Shai Meretzki
- 31.2\* Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Yossi Keret
- (32) Section 1350 Certifications
- 32.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLURISTEM LIFE SYSTEMS, INC.

By: /s/ Shai Meretzi  
Shai Meretzki, Chief Executive Officer  
(Principal Executive Officer)

Date: November 19 , 2004

By: /s/ Yossi Keret

Yossi Keret, Chief Accounting Officer

(Principal Financial Officer and Principal Accounting Officer)

Date: November 19 , 2004

Exhibit 31.1

CERTIFICATION PURSUANT TO  
18 U.S.C. ss.1350, AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shai Meretzki, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Pluristem Life Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 19 , 2004

/s/ Shai Meretzki

Shai Meretzki  
Chief Executive Officer  
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO  
18 U.S.C. ss.1350, AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yossi Keret, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Pluristem Life Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 19 , 2004

/s/ Yossi Keret

Yossi Keret  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Shai Meretzki, Chief Executive Officer, and Yossi Keret, Chief Financial Officer of Pluristem Life Systems, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Quarterly Report on Form 10-QSB of Pluristem Life Systems, Inc. for the quarterly period ended September 30, 2004 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Pluristem Life Systems, Inc.

By:  
/s/ Shai Meretzki  
Chief Executive Officer  
Dated: November 19 , 2004

By:  
/s/ Yossi Keret

Chief Financial Officer

Dated: November 19 , 2004

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Pluristem Life Systems, Inc. and will be retained by Pluristem Life Systems, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.