

PLURISTEM LIFE SYSTEMS INC  
Form 10QSB  
February 13, 2007  
UNITED STATES

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-QSB**

(Mark One)

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

For the quarterly period ended **December 31, 2006**

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**

(State or other jurisdiction of incorporation or organization)

**98-0351734**

(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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

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**

Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 267,065,997 common shares issued and outstanding as of February 7, 2007

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

---

**PART I - FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

It is the opinion of management that the consolidated interim financial statements for the quarter ended December 31, 2006, include all adjustments necessary in order to ensure that the consolidated interim financial statements are not misleading.

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**CONSOLIDATED FINANCIAL STATEMENTS**

**As of December 31, 2006**

**IN U.S. DOLLARS**

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**CONSOLIDATED FINANCIAL STATEMENTS**

**As of December 31, 2006**

**IN U.S. DOLLARS**

**INDEX**

	<b><u>Page</u></b>
Consolidated Balance Sheet	2-3
Consolidated Statements of Operations	4
Statements of changes in Stockholders' Equity (Deficiency)	5-10
Consolidated Statements of Cash Flows	11-12
Notes to Consolidated Financial Statements	13-30

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**CONSOLIDATED BALANCE SHEET (UNAUDITED)**

**In U.S. Dollars**

	<b>December 31, 2006</b>
<b>ASSETS</b>	
CURRENT ASSETS:	
Cash and cash equivalents	\$ 842,880
Prepaid expenses	20,294
Other accounts receivables	82,316
<u>Total current assets</u>	945,490
LONG-TERM RESTRICTED LEASE DEPOSIT	51,599
SEVERANCE PAY FUND	62,882
PROPERTY AND EQUIPMENT, NET	324,946
DEFERRED ISSUANCE EXPENSES	7,766
<u>Total assets</u>	\$ 1,392,683

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 SHEET (UNAUDITED)**

**In U.S. Dollars**

	<b>December 31, 2006</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>	
<b>CURRENT LIABILITIES:</b>	
Short-term bank credit	\$ 41
Know-how licensors	218,751
Trade payables	186,580
Accrued expenses	172,207
Other accounts payable	86,677
<u>Total</u> current liabilities	664,256
<b>LONG-TERM LIABILITIES</b>	

Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

Accrued severance pay	76,241
<b>STOCKHOLDERS EQUITY</b>	
Share capital:	
Common stock \$0.00001 par value:	
Authorized: 1,400,000,000 shares	
Issued and Outstanding: 267,695,684 shares	2,676
Additional paid-in capital	8,704,830
Deficit accumulated during the development stage	(8,055,320)
	652,186
	\$ 1,392,683

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

F-3

---



**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**In U.S. Dollars (except share and per share data)**

	<b>Six Month Period Ended December</b>		<b>Three Month Period Ended December</b>		<b>Period From May 11,</b>
	<b>31,</b>		<b>31,</b>		<b>2001 (Inception)</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>	<b>Through</b>
					<b>December 31,</b>
					<b>2006</b>
Research and development costs, net	\$ 548,389	\$ 520,177	\$ 158,780	\$ 266,871	\$ 4,637,350
General and administrative expenses	861,887	412,679	456,237	203,770	5,055,796
In-process research and development write-off	-	-	-	-	246,470
	1,410,276	932,856	615,017	470,641	9,939,616
Financial expenses (income), net	(444,036)	(71,690)	67,162	15,376	(1,884,296)
Net loss for the period	\$ 966,240	\$ 861,166	\$ 682,179	\$ 486,017	\$ 8,055,320
Basic and diluted net loss per share	\$ (0.006)	\$ (0.01)	\$ (0.003)	\$ (0.01)	
Weighted average number of shares used in computing basic and diluted net loss per share:	152,129,517	63,653,483	235,030,469	63,653,483	

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

F-4

---

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY) (UNAUDITED)  
In U.S. Dollars (except shares data)**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Additional paid-in Capital</b>	<b>Receipts On account of shares</b>	<b>Deficit Accumulated during the Development Stage</b>	<b>Total Stockholders Equity (Deficiency)</b>
Issuance of common stock on July 9, 2001	35,000,000	\$ 350	\$ 2,150	\$ -	\$ -	\$ 2,500
<b>Balance as of June 30, 2001</b>	35,000,000	350	-	-	-	2,500
Net loss	-	-	-	-	(77,903)	(77,903)
<b>Balance as of June 30, 2002</b>	35,000,000	350	2,150	-	(77,903)	(75,403)
Issuance of common stock on October 14, 2002,						
Net of issuance expenses of \$17,359	14,133,000	141	83,450	-	-	83,591
Forgiveness of debt	-	-	11,760	-	-	11,760
Stocks cancelled on March 19, 2003	(27,300,000)	(273)	273	-	-	-
Receipts on account of stock and warrants, net of finders and legal fees of \$56,540	-	-	-	933,464	-	933,464
Net loss	-	-	-	-	(462,995)	(462,995)
<b>Balance as of June 30, 2003</b>	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 (DEFICIENCY) (UNAUDITED)**  
**In U.S. Dollars (except share and per share data)**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Additional paid-in Capital</b>	<b>Receipts on account of shares</b>	<b>Deficit accumulated During the development stage</b>	<b>Total Shareholders Equity (Deficiency)</b>
<b>Balance as of July 1, 2003</b>	21,833,000	\$ 218	\$ 97,633	\$ 933,464	\$ (540,898)	\$ 490,417
Issuance of common stock on July 16, 2003, net of issuance expenses of \$70,110	725,483	7	1,235,752	(933,464)	-	302,295
Issuance of common stock on January 20, 2004	3,000,000	30	-	-	-	30
Issuance of warrants on January 20, 2004 for finder's fee	-	-	192,000	-	-	192,000
Common stock granted to consultants on February 11, 2004	1,000,000	10	799,990	-	-	800,000
Stock based compensation related to warrants granted to consultants on December 31, 2003	-	-	357,618	-	-	- 357,618
Exercise of warrants on April 19, 2004	300,000	3	224,997	-	-	225,000
Net loss for the year	-	-	-	-	(2,010,350)	(2,010,350)
<b>Balance as of June 30, 2004</b>	26,858,483	\$ 268	\$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 (DEFICIENCY) (UNAUDITED)  
In U.S. Dollars (except share and per share data)**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Additional paid-in capital</b>	<b>Deficit accumulated During the development stage</b>	<b>Total Shareholders Equity (Deficiency)</b>
<b>Balance as of July 1, 2004</b>	26,858,483	\$ 268	\$ 2,907,990	\$ (2,551,248)	\$ 357,010
Stock-based compensation related to warrants granted to consultants on September 30, 2004	-	-	161,641	-	161,641
Issuance of common stock and warrants on November 30, 2004 related to the October 2004 Agreement net of issuance costs of \$28,908	3,250,000	33	296,059	-	296,092
Issuance of common stock and warrants on January 26, 2005 related to the October 2004 Agreement net of issuance costs of \$4,975	4,300,000	43	424,982	-	425,025
Issuance of common stock and warrants on January 31, 2005 related to the January 31, 2005 Agreement	7,000,000	70	-	-	70
Issuance of common stock and options on February 15, 2005 to former director of the company	50,000	(*)	14,500	-	14,500
Issuance of common stock and warrants on February 16, 2005 related to the January 31, 2005 Agreement	5,000,000	50	-	-	50

(\*) Less than one dollar

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

F-7

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY) (UNAUDITED)  
In U.S. Dollars (except share and per share data)**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Additional paid-in capital</b>	<b>Deficit accumulated During the development stage</b>	<b>Total Shareholders Equity (Deficiency)</b>
Issuance of warrants on February 16, 2005 for finder fee related to the January 31, 2005 Agreement	-	-	144,000	-	144,000
Issuance of common stock and warrants on March 3, 2005 related to the January 24, 2005 Agreement net of issuance costs of \$24,000	12,000,000	120	1,175,880	-	1,176,000
Issuance of common stock on March 3, 2005 for finder fee related to the January 24, 2005 Agreement	1,845,000	18	(18)	-	-
Issuance of common stock and warrants on March 3, 2005 related to the October 2004 Agreement net of issuance costs of \$6,038	750,000	8	68,954	-	68,962
Issuance of common stock and warrants to the Chief Executive Officer on March 23, 2005	2,400,000	24	695,976	-	696,000
Issuance of common stock on March 23, 2005 related to the October 2004 Agreement	200,000	2	19,998	-	20,000

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) (UNAUDITED)**  
**In U.S. Dollars (except share and per share data)**

	<b>Common Stock Shares</b>	<b>Amount</b>	<b>Additional paid-in capital</b>	<b>Deficit accumulated during the development stage</b>	<b>Total Shareholders Equity (Deficiency)</b>
Classification of a liability in respect of warrants to additional paid in capital, net of issuance costs of \$ 178,116	-	-	541,884	-	541,884
Net loss for the year	-	-	-	(2,098,108)	(2,098,108)
<b>Balance as of June 30, 2005</b>	63,653,483	636	6,451,846	(4,649,356)	1,803,126
Exercise of warrants on November 28, 2005 to finders related to the January 24, 2005 agreement	80,000	(*)	-	-	-
Exercise of warrants on January 25 ,2006 To finders related to the January 25, 2005 Agreement	10,000	(*)	-	-	-
Reclassification of warrants from equity To liabilities due to application of EITF 00-19 (**)	-	-	(7,632)	-	(7,632)
Net loss for the year	-	-	-	(2,439,724)	(2,439,724)
<b>Balance as of June 30, 2006</b>	63,743,483	\$ 636	\$ 6,444,214	\$ (7,089,080)	\$ (644,230)

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) (UNAUDITED)  
In U.S. Dollars (except share and per share data)**

	Common Stock Shares	Amount	Additional paid-in capital	Deficit accumulated during the development stage	Total Shareholders Equity (Deficiency)
<b>Balance as of July 1, 2006</b>	63,743,483	\$ 636	\$ 6,444,214	\$ (7,089,080)	\$ (644,230)
Conversion of convertible debenture, net of issuance costs	203,952,201	2,040	1,785,044	-	1,787,084
Classification of a liability in respect of warrants to additional paid in capital	-	-	359,658	-	359,658
Classification of deferred issuance expenses to additional paid in capital	-	-	(378,708)	-	(378,708)
Compensation related to options granted to employees	-	-	317,361	-	317,361
Classification of a liability in respect of options granted to consultants	-	-	177,261	-	177,261
Net loss for the period	-	-	-	(966,240)	(966,240)
<b>Balance as of December 31, 2006</b>	267,695,684	\$ 2,676	\$ 8,704,830	\$ (8,055,320)	\$ 652,186

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 (UNAUDITED)****In U.S. Dollars**

	<b>Six months ended December 31,</b>		<b>Period from May</b>
	<b>2006</b>	<b>2005</b>	<b>11, 2001 (inception)</b>
			<b>through December</b>
			<b>31</b>
			<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (966,240)	\$ (861,166)	\$ (8,055,320)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	24,209	20,668	210,778
Capital gain	-	-	(16,373)
Impairment of know-how	-	-	264,807
Amortization of deferred issuance costs	160,462	69,868	585,604
Stock-based compensation to employees	317,362	-	317,362
Stock-based compensation to consultants	60,890	-	1,242,022
In-process research and development write-off	-	-	246,470
Know-how licensors imputed interest	-	18,791	54,600
Salary grant in shares and warrants	-	-	710,500
Decrease (increase) in accounts receivable	18,755	93,191	(73,480)
Decrease in prepaid expenses	42,029	48,914	69,706
Increase (decrease) in trade payables	(98,523)	(44,097)	177,173
Increase (decrease) in other accounts payable and accrued expenses	28,356	(39,862)	(273,975)
Increase in accrued interest due to related parties	-	-	3,450
Linkage differences and interest on long-term restricted lease deposit	-	(80)	(2,164)
Change in fair value of liability in respect of warrants	(716,214)	(150,000)	(2,539,177)
Change in convertible debenture	161,332	-	161,332
Accrued severance pay, net	(6,336)	4,947	13,359
Net cash used in operating activities	(973,918)	(838,826)	(6,903,326)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisition of Pluristem Ltd. (1)	-	-	31,899
Purchase of property and equipment	(94,461)	(28,475)	(337,233)
Proceed from sale of property and equipment	-	-	28,475
Purchase of long-term restricted lease deposit	(22,934)	(3,653)	(50,479)
Repayment of long-term restricted lease deposit	-	-	19,851
Purchase of know-how	-	-	(100,000)
Net cash used in investing activities	(117,395)	(32,128)	(407,487)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Issuance of common stock, net of issuance costs	-	-	4,686,209
Issuance of warrants	-	-	1,246,397
Issuance of convertible debenture	-	-	2,734,012
Issuance expenses	(440,000)	-	(440,000)
Short-term bank credit, net	41	-	15
Repayment of know-how licensors	-	-	(151,135)

Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

Proceeds from notes and loan payable to related parties	-	-	78,195
Net cash provided by financing activities	(439,959)	-	8,153,693
Increase (decrease) in cash and cash equivalents	(1,531,272)	(870,954)	842,880
Cash and cash equivalents at the beginning of the period	2,374,152	1,889,438	-
Cash and cash equivalents at the end of the period	\$ 842,880	\$ 1,018,484	\$ 842,880

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

F-11

---

**PLURISTEM LIFE SYSTEMS INC. AND ITS SUBSIDIARY**

(A Development Stage Company)

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

**In U.S. Dollars**

	<b>Six months ended December 31,</b>		<b>Period from May</b>
	<b>2006</b>	<b>2005</b>	<b>11, 2001</b>
			<b>(inception)</b>
			<b>through</b>
			<b>December 31,</b>
			<b>2006</b>
<b>Non-cash investing and financing information:</b>			
Unpaid know-how	\$ -	\$ -	\$ 218,750
Conversion of convertible debenture	\$2,227,084	\$ -	\$ 2,227,084
<b>(1) Acquisition of Pluristem Ltd.</b>			
<b>Fair value of assets acquired and liabilities assumed at the acquisition date:</b>			
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 \$8,055,320 through December 31, 2006. 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 that might arise from this uncertainty, 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 December 31, 2006, 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 six-month period ended December 31, 2006 are not necessarily indicative of the results that may be expected for the year ended June 30, 2007.

**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 followed in the preparation of these financial statements are identical to those applied in the preparation of the latest annual financial statements except as detailed in b below.

Certain amounts from prior year have been reclassified to conform to current period presentation.

- b. On July 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") which requires the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to employees and directors. SFAS 123(R) supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ("SAB 107") relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

SFAS 123(R) requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated income statement. Prior to the adoption of SFAS 123(R), the Company accounted for equity-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123").

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard starting from July 1, 2006, the first day of the Company's fiscal year 2006. Under that transition method, compensation cost recognized in the six months period ended December 31, 2006, includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of July 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement 123, and (b) compensation cost for all share-based payments granted subsequent to July 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Results for prior periods have not been restated.

The Company recognizes compensation expenses for the value of its awards, which have graded vesting based on the straight line method over the requisite service period of each of the awards.

Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

As a result of adopting SFAS 123(R) as of July 1, 2006, the Company's net income for the six months ended December 31, 2006, is \$324,993 lower than if it had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share for the six months ended December 31, 2006, are \$ 0.002 lower, than if the Company had continued to account for share-based compensation under APB 25.

F-14

---

**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)**

b. (cont.)

Prior to July 1, 2006, the Company applied the intrinsic value method of accounting for stock options as prescribed by APB 25, whereby compensation expense is equal to the excess, if any, of the quoted market price of the stock over the exercise price at the grant date of the award.

The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are, expected stock price volatility, and the expected option term. Expected volatility was calculated based upon actual historical stock price movements over the most recent periods ending on the grant date, equal to the expected option term. The expected option term represents the period that the Company's stock options are expected to be outstanding and was determined based on historical experience of similar options, giving consideration to the contractual terms of the stock options. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term.

The fair value of the Company's stock options granted to employees and directors for the six months ended December 31, 2006 and 2005 was estimated using the following weighted average assumptions:

	<b>Six months ended</b>	
	<b>December 31, 2006</b>	<b>2005</b>
	<b>Unaudited</b>	
Risk free interest rate	4.3-4.5%	3.8%
Dividend yields	0%	0%
Volatility	105%	112%
Expected term (in years)	6-8	9.5





**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)**

b. (cont.)

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

	<b>Six months ended December 31 2005</b>	<b>Three months ended December 31 2005</b>	<b>Period from May 11, 2001 (Inception) through June 30 2006</b>
Net loss available to Common stock as Reported	\$ 861,166	\$ 486,017	\$8,055,320
Deduct- stock-based employee compensation- intrinsic value	-	-	(26,393)
Add - stock based employee compensation -fair value	56,898	22,419	981,578
Pro forma net loss	\$ 918,064	\$ 508,436	\$ 9,010,505
Basic and diluted net loss per stock as reported			
	\$ (0.01)	\$ (0.01)	
Basic and diluted pro forma net loss per stock			
	\$ (0.01)	\$ (0.01)	

c. Recently issued accounting pronouncements:

1. FASB Interpretation No. 48:

In July 2006, the FASB issued FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the

financial statements. FIN 48 utilizes a two-step approach for evaluating tax positions. Recognition (step one) occurs when an enterprise concludes that a tax position, based solely on its technical merits, is more-likely-than-not to be sustained upon examination. Measurement (step two) is only addressed if step one has been satisfied (i.e., the position is more-likely-than-not to be sustained). Under step two, the tax benefit is measured as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement.

**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)**

c. Recently issued accounting pronouncements (continued):

1. FASB Interpretation No. 48 (cont.):

FIN 48 applies to all tax positions related to income taxes subject to the Financial Accounting Standard Board Statement No. 109, "Accounting for income taxes" ("FAS 109"). This includes tax positions considered to be "routine" as well as those with a high degree of uncertainty.

FIN 48 has expanded disclosure requirements, which include a tabular roll forward of the beginning and ending aggregate unrecognized tax benefits as well as specific detail related to tax uncertainties for which it is reasonably possible the amount of unrecognized tax benefit will significantly increase or decrease within twelve months. These disclosures are required at each annual reporting period unless a significant change occurs in an interim period.

FIN 48 is effective for fiscal years beginning after December 15, 2006. The cumulative effect of applying FIN 48 will be reported as an adjustment to the opening balance of retained earnings. The Company does not expect that the adoption of FIN 48 will have a significant impact on the Company's financial position and results of operations.

SFAS No. 157:

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("SFAS No. 157"). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations. The statement does not apply to accounting standard that require or permit measurement similar to fair value but are not intended to represent fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of adopting SFAS 157.

2. Staff Accounting Bulletin No. 108:

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108") Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, that provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and

F-17

---

**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)**

c. Recently issued accounting pronouncements (continued):

3. Staff Accounting Bulletin No. 108 (cont.):

qualitative factors are considered, is material. This pronouncement is effective for fiscal years ending after November 15, 2006. The Company is currently evaluating the provisions of SAB 108.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108") Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, that provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. This pronouncement is effective for fiscal years ending after November 15, 2006. The Company is currently evaluating the provisions of SAB 108.

**NOTE 3: - SHARE CAPITAL AND STOCK OPTIONS**

a. The Company's authorized common stock consists of 1,400,000,000 shares with a par value of \$0.00001 per share. All shares have equal voting rights and are entitled to one vote per share in all matters to be voted upon by stockholders. The shares have no pre-emptive, subscription, conversion or redemption rights and may be issued only as fully paid and non-assessable shares. Holders of the common stock are entitled to equal ratable rights to dividends and distributions with respect to the common stock, as may be declared by the Board of Directors out of funds legally available. The common stocks are registered and publicly traded on the Over-the-Counter Bulletin Board service of the National Association of Securities Dealers, Inc. under the symbol PLRS.OB.

b. On July 9, 2001, the Company issued 35,000,000 shares of common stock in consideration for \$2,500, which was received on July 27, 2001.

On October 14, 2002, the Company issued 14,133,000 shares of common stock at a price of \$0.007 per common share in consideration for \$100,950 before offering costs of \$17,359.

c. On March 19, 2003, two directors each returned 13,650,000 shares of common stock with a par value of \$0.01 per share, for cancellation for no consideration.

d. On March 27, 2003 the Company's Board of Directors authorized a 14:1 split of the common stock. Accordingly, all references to number of shares, common stock and per share data in the accompanying financial statements have been adjusted to reflect the stock split on a retroactive basis.



**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

- e. In July 2003, the Company issued an aggregate of 725,483 units comprised of 725,483 common stock and 1,450,966 warrants to a group of investors, for total consideration of \$1,235,752 (net of issuance costs of \$70,110), under a private placement. The consideration was paid partly in the year ended June 30, 2003 (\$933,464) and the balance was paid in the year ended June 30, 2004. In this placement each unit was comprised of one common stock and two warrants, the first warrant is exercisable for one common stock at a price of \$2.25 per stock, and may be exercised within one year. The second warrant is exercisable for one common stock at a price of \$2.70 per stock, and may be exercised within five years. As of June 30, 2005, 725,483 warrants were expired unexercised.
- f. On January 20, 2004, the Company consummated a private equity placement with a group of investors (the "investors"). The Company issued 3,000,000 units in consideration for net proceeds of \$1,272,790 (net of issuance costs of \$227,210), each unit is comprised of 3,000,000 common stock and 3,000,000 warrants. Each warrant is exercisable into one common stock at a price of \$0.75 per stock, and may be exercised until January 31, 2007. If the price of the common stock will be more than \$1 within 10 consecutive trading days, then the Company may, by notice to the warrants' holders, reduce the expiry date of 1,500,000 warrants to 60 days from the day of notice. In case the Company fails to register the above-mentioned shares and the related shares resulting from the exercise of the warrants, it will be subject to penalties as detailed in the private placement agreement. On March 18, 2004, a registration statement on Form SB-2 has been declared affective and the above-mentioned common stocks have been registered for trading. If the effectiveness of the Registration Statement is suspended subsequent to the effective date of registration (March 18, 2004), for more than certain permitted periods, as described in the private equity placement agreement, the Company shall pay penalties to the investors in respect of the liquidated damages.

According to EITF 00-19, "Accounting for derivative financial instruments indexed to, and potentially settled in, a Company's own stock", the Company classified the warrants as liabilities according to their fair value as remeasured at each reporting period until exercised or expired. Changes in the fair value of the warrants will be reported in the statements of operations as financial income or expense.

As of June 20, 2004, the Company allocated the gross amount received of \$1.5 million to the par value of the shares issued (\$30) and to the liability in respect of the warrants issued (\$1,499,970). The amount allocated to the liability was less than the fair value of the warrants at grant date. As of December 31, 2006, the fair value of the liability in respect for the warrants issued was \$0. The fair value as of December 31, 2006 was estimated using the Black-Scholes option pricing model with the following weighted average assumptions: risk-free interest rate of 4.3%, expected dividend yield of 0%, expected volatility of 105%, and expected life of 0.08 years.



**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

f. (cont.)

The change in the carrying amount of the liability in respect of the warrants in the amount of \$270,000, \$150,000 and \$0 for the year ended June 30, 2005 and 2006 and for the six months ended December 31, 2006, respectively was recognized in the statements of operations as financial income.

In addition, the Company issued 300,000 warrants to finders in connection with this private placement, exercisable into 300,000 common shares at a price of \$0.75 per common share until January 31, 2007. The fair value of the warrants issued in the amounts of \$192,000 was recorded as deferred issuance costs and is amortized over a period of 3 years. On April 19, 2004, the finders exercised the warrants. The fair value of the warrants was estimated using the Black-Scholes option pricing model under the same weighted average assumptions.

g. In October 2004 the Company commenced a private placement offering ( the October 2004 Agreement ) according to which it issued 8,500,000 units. Each unit is comprised of one common stock and one warrant. The warrant is exercisable for one common stock at an exercise price of \$0.30 per stock, subject to certain adjustments. The units were issued as follows:

In November 2004, the Company issued according to the October 2004 Agreement 3,250,000 units comprised of 3,250,000 common stock and 3,250,000 warrants to a group of investors, for total consideration of \$296,092 (net of cash issuance costs of \$28,908), and additional 120,000 warrants to finders as finders fee.

In January 2005 the Company issued according to the October 2004 Agreement an additional 4,300,000 units for total consideration of \$425,025 (net of cash issuance costs of \$4,975), and additional 90,000 warrants were issued to finders as finders fee.

In March 2005 the Company issued according to the October 2004 Agreement additional 750,000 units for total consideration of \$68,962 (net of cash issuance costs of \$6,038), and additional 35,000 warrants were issued to finders as finders fee.

In March 2005 the Company issued, according to the October 2004 Agreement 200,000 common shares and 200,000 share purchase warrants to one investor for total consideration of \$20,000 which were paid to the Company in May 2005.

As for December 31, 2006, all the warrants were expired unexercised.

**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

- h. On January 24, 2005 the Company commenced a private placement offering (the January 24, 2005 Agreement ) which was closed on March 3, 2005 and issued 12,000,000 units in consideration for \$1,176,000 (net of cash issuance costs of \$24,000). Each unit is comprised of one common stock and one warrant. The warrant is exercisable for one common stock at a price of \$0.30 per stock. As for December 31, 2006, all the warrants were expired unexercised. Under this agreement the Company issued to finders 1,845,000 shares and 475,000 warrants with exercise price of \$2.5 per stock exercisable until November 2007.
- i. On January 31, 2005, the Company consummated a private equity placement offering (the January 31, 2005 Agreement ) with a group of investors (the "Investors") according to which it issued 12,000,000 units in consideration for net proceeds of \$1,137,000 (net of issuance costs of \$63,000). Each unit is comprised of one common stock and one warrant. Each warrant is exercisable into one common stock at a price of \$0.30 per stock. If the Registration Statement covering the Registrable Securities was not filed as contemplated by 70 days and if the Registration Statement covering the Registrable Securities was not effective until August 31, 2005, The Company would have paid the Investor 2% of the purchase price for each 30 day period beyond the applicable date until the filing or the registration is completed. The January 31, 2005 Agreement includes a finder's fee of a cash amount equal to 5% of the amount invested (\$60,000) and issuance of warrants for number of shares equal to 5% of the number of shares that were issued (600,000) with an exercise price of \$0.1 per stock, subject to certain adjustments, exercisable until November 30, 2006.

According to EITF 00-19, "Accounting for derivative financial instruments indexed to, and potentially settled in, a Company's own stock", the Company classified the warrants as liabilities according to their fair value as remeasured at each reporting period until exercised or expired. Changes in the fair value of the warrants will be reported in the statements of operations as financial income or expense.

As of the date of the issuance the Company allocated the gross amount received of \$1,200,000 to the par value of the shares issued (\$120) and to the liability in respect of the warrants issued (\$1,199,880). Issuance expenses in the amount of \$63,000 and finders fee in the amount of \$144,000 were recorded as deferred issuance costs. The amount allocated to the liability was less than the fair value of the warrants at grant date. On May 13, 2005 the Registration Statement became effective and the Company became no longer under possible penalties. As such, the liability and the deferred issuance costs related to the agreement has been classified to the Stockholders Equity as Additional Paid in Capital. As of May 13, 2005, the fair value of the liability in respect of the warrants issued was \$720,000 and the amount of the deferred issuance costs was \$178,116. The change in the carrying amount of the liability in respect of the warrants, recorded as income, in the year ended June 30, 2005 amounted to \$479,880.

**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

i. (cont.)

The fair value as of May 13, 2005 was estimated using the Black-Scholes option pricing model with the following weighted average assumptions: risk-free interest rate of 3.75%, expected dividend yield of 0%, expected volatility of 104%, and expected life of 1.54 years.

As for December 31, 2006, all the warrants were expired unexercised.

- j. On March 23, 2005, the Company issued 2,400,000 shares of common stock and 2,400,000 options as a bonus to the chief executive officer, Dr. Shai Meretzki, in connection with the issuance of a Notice of Allowance by the United States Patent Office for patent application number 09/890,401. Salary expenses of \$696,000 were recognized in respect of this bonus based on the quoted market price of the Company's stock and the fair value of the options granted using the Black Scholes valuation model. As for December 31, 2006, all the warrants were expired unexercised.
- k. On February 11, 2004, the Company issued an aggregate amount of 1,000,000 common stock to a consultant and service provider as compensation for carrying out investor relations activities during the year 2004. Total compensation, measured as the grant date fair market value of the stock, amounted to \$800,000 and was recorded as an operating expense in the statement of operations in the year ended June 30, 2004.
- l. On November 28, 2005, 80,000 warrants, which were issued to finders as finder fees in related to the January 24, 2005 Agreement , were exercised to shares.
- m. On January 25, 2006, 10,000 warrants, which were issued to finders as finder fees in related to the January 24, 2005 Agreement , were exercised to shares.
- n. Stock Option Plan 2003 ("ESOP")

Under the Company's 2003 Stock Option Plan (the "2003 Plan"), options may be granted to officers, directors, employees and consultants of the Company or its subsidiary.

Pursuant to the 2003 Plan, the Company reserved for issuance 4,100,000 of its common stock. As of December 31, 2006, 68,941 common stock of the Company are still available for future grant under the terms of the 2003 Plan.

Each option granted under the 2003 Plan is exercisable through the expiration date of the 2003 Plan which is December 2013 unless stated otherwise. The exercise price of the options granted under the 2003 plan may not be less than the nominal value of the stock into which such options are exercised. The options vest primarily over two years. Any option which are cancelled or forfeited before expiration, become available for future grants.



**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

n. Stock Option Plan 2005 ("ESOP")

Under the Company's 2005 Stock Option Plan (the "2005 Plan"), options may be granted to officers, directors, employees and consultants of the Company or its subsidiary.

Pursuant to the 2005 Plan, the Company reserved for issuance 15,000,000 of its common stock.

Each option granted under the 2005 Plan is exercisable through the expiration date of the 2005 Plan which is January 2016 unless stated otherwise. The exercise price of the options granted under the 2005 plan may not be less than the nominal value of the stock into which such options are exercised. The options vest primarily over two years. Any option which are cancelled or forfeited before expiration, become available for future grants.

Options to employees:

On December 2003, the Company granted 2,976,591 options to employees and directors at an exercise price of \$0.76. All options were granted with an exercise price that exceeded the quoted market price of the Company's stock on the date of grant. Fair value (determined using the Black-Scholes valuation model) of each option granted was \$0.29 at date of grant. During the period ended June 30, 2004, 156,734 options to employees were forfeited.

During the year ended June 30, 2005, 451,170 options were granted to the Company's Chief Financial Officer and 239,683 options were granted to directors of the Company. On February 15, 2005 the Company issued 50,000 shares and 70,495 options to former director and Chief Executive Officer of the Company. The exercise price of the options is \$0.3 per share and they are fully vested and exercisable till February 15, 2008. During the year ended June 30, 2005, 15,415 options to employees were forfeited.

On October 17, 2004 the Board of Directors decided to reduce the exercise price of the options that were granted to the Company's employees and directors from \$0.76 to \$0.3. On September 21, 2005 the Board of directors decided to reduce the exercise price of the options that were granted to the Company's employees and directors from \$0.3 to \$0.12. According to APB Opinion No. 25 and FIN 44 when the exercise price of a fixed stock option award is reduced, the award shall be accounted for as a variable plan from the date of modification to the date the award is exercised, forfeited, or expires unexercised.

On September 21, 2005 the Board of Directors appointed a new Chief Executive Officer, and approved to grant him 4,500,000 stock options exercisable at a price of \$0.12 per share to be vested over a three years period. On January 17, 2006 the Company granted him the stock options from the 2005 plan and resolved to reduce the exercise price to \$0.1 and to revise the vesting period to two years. The reduction of the exercise price did not result in additional compensation expenses. Till June 30, 2006 the award was accounted for as a variable plan from the date of modification.

**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**

F-23

**NOTE 3: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

On January 17, 2006, the Company granted 5,490,000 stock options to employees and directors. The options have a two years vesting period with six months grace period (i.e. vesting equally monthly during the remaining 18 months). The option's exercise price was determined to be the stock price at the date of grant which was \$0.1. Fair value (determined using the Black-Scholes valuation model) of options granted was \$0.08 per option at date of grant.

On October 30, 2006 the Board of Directors decided to reduce the exercise price of the options that were granted to the Company's employees and directors from \$ 0.1 to \$0.022. According to SFAS 123(R) modifications are treated as an exchange of the original award, resulting in additional compensation expenses based on the differences between the fair value of the new award and the original award immediately before modification. The incremental expenses should be expensed over the remaining vesting period.

As a result, the Company recognized compensation expenses of \$46,196 immediately for the options that were already fully vested and the remaining compensation expenses amounted to \$7,632 will be expense through the remaining vesting period of the options. The fair value for these options was estimated using Black-Scholes option-pricing model.

On September 18, 2006 the Board of Directors approved to grant to two officers 8,500,000 stock options exercisable at a price of \$0.022 per share. The options have a two years vesting period with six months grace period (i.e. vesting equally monthly during the remaining 18 months). The fair value for these options at the grant date was \$140,678.

On November 21, and December 27, 2006 the Company granted 6,590,000 options exercisable at a price of \$0.019-\$0.022 per share to the Company's employees and directors under the 2005 Plan. The fair value for these options at the grant date was \$109,672.

Options to consultants:

In the framework of the stock option plan, the Company issues options to consultants, for carrying out investor relation's activities. On December 2003, the Company granted 669,189 options to consultants at a weighted average exercise price of \$0.92.

In July 2004, the Company's Board of Directors approved to modify the terms of 500,000 options granted to a consultant on December 2003 (of which 250,000 are with an exercise price of \$1 and 250,000 with an exercise price of \$1.25) 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, vested immediately and with a cashless exercise feature. The additional 500,000 options were granted outside of the terms of the options plan. In June 2005 the consultant agreed to cancel the 1,000,000 options and to be granted 600,000 shares of the Company's common stock. Since the fair value of the options that were cancelled and the shares that were issued were equal, no additional compensation expenses were recorded.

F-24

---

**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

On November 21, 2005 the Board of Directors approved Dr. Shai Maretzki's consulting agreement with the Company for a period of 2.5 years. Under this agreement the Company granted him 1,500,000 stock options under the ESOP and upon the formal approval of the plan by Tax Authorities. The options will have a two years vesting period with six months grace period (i.e. vesting equally monthly during the remaining 18 months). The options were granted on January 17, 2006 at the exercise price of \$0.10.

On January 17, 2006, the Company granted to consultants 1,150,000 stock options from the 2005 Plan. The options have a two years vesting period with six months grace period (i.e. vesting equally monthly during the remaining 18 months). The options' exercise price is \$0.10.

The grant date fair value for these options amounts to \$94,853.

On October 30, 2006 the Board of Directors decided to reduce the exercise price of the options that were granted to the Company's consultants from \$ 0.1 to \$ 0.022. According to SFAS 123(R) modifications are treated as an exchange of the original award, resulting in additional compensation based on the differences between the fair value of the new award and the original award immediately before modification in the amount of \$8,335. The incremental expenses in the amount of \$1,838 should be expensed over the remaining vesting period.

On October 30, 2006 the Company granted 750,000 options to consultant under the 2005 Plan. The grant date fair value for these options amounts to \$12,413.

On December 27, 2006 the Company granted 1,250,000 options to consultant under the 2005 plan. The grant date fair value for these options amounts to \$20,783.

During the six month period ended December 31, 2006, 150,000 of the options were forfeited.

The Company accounted for its options to consultants under the fair value method in accordance of SFAS 123 and EITF 96-18. The fair value for these options was estimated using Black-Scholes option-pricing model with the following weighted-average assumptions: risk-free interest rates of 4.3-4.56%, expected dividend yield of 0%, expected volatility of 105%, and a weighted-average contractual life of the warrants of up to 10 years. Compensation expenses of \$60,890 were recognized during the six months period ended December 31, 2006, in respect with those options.



**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

A summary of the Company's share option activity (except options to consultants) under the Plans is as follows:

	<b>Six months ended December 31, 2006</b>		<b>Weighted average remaining contractual terms (in years)</b>	<b>Aggregate intrinsic value price</b>
	<b>Number</b>	<b>Weighted Average Exercise Price</b>		
Options outstanding at beginning of year	13,555,790	\$ 0.033		
Options granted	15,090,000	\$ 0.021		
Options exercised	-	\$ -		
Options forfeited	(88,334)	\$ 0.022		
Options outstanding at end of the period	28,557,456	\$ 0.027	8.98	\$ 7,690
Options exercisable at the end of the period	7,171,106	\$ 0.041	7.92	\$ -
Options vested and expected to vest	7,171,106	\$ 0.041	7.92	\$ -

The Company's outstanding options to employees as of December 31, 2006, have been separated into ranges of exercise prices as follows:

<b>Issuance date</b>	<b>Options for Ordinary Shares</b>	<b>Exercise Price per Share</b>	<b>Options Exercisable</b>	<b>Weighted average remaining contractual terms</b>
January 2003- June 2005	3,565,790	\$ 0.022-0.12	3,326,107	6.58
January 2006	9,901,666	\$ 0.022	3,844,999	9.09
September 2006-	8,500,000	\$ 0.022	-	9.09

Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

November 2006  
December 2006

6,590,000      \$ 0.019-0.022      -      10

F-26

---

**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: - SHARE CAPITAL AND STOCK OPTIONS (CONT.)**

Compensation expenses related to options granted to employees were recorded to research and development expenses and general and administrative expenses, as follows:

	<b>Six months ended December 31,</b>		<b>Period from</b>
	<b>2006</b>	<b>2005</b>	<b>inception through</b>
			<b>December 31,</b>
			<b>2006</b>
Research and development expenses	\$ 48,578	-	\$ 48,578
General and administrative expenses	268,784	-	268,784
	\$ 317,362	-	\$ 317,362

The Company's outstanding options to non-employees as of December 31, 2006, have been separated into ranges of exercise prices as follows:

<b>Issuance date</b>	<b>Options for Ordinary Shares</b>	<b>Exercise Price per Share</b>	<b>Options Exercisable</b>	<b>Weighted average remaining contractual terms</b>
December 31, 2003	169,189	\$ 0.4	169,189	6.34
January 17, 2006	2,500,000	\$ 0.022	1,145,833	9.09
October 30, 2006	750,000	\$ 0.022	-	9.09
December 27, 2006	1,250,000	\$ 0.019	-	10

- o. During the six months period ended December 31, 2006, the Company issued 193,952,201 shares to the owners of Senior Secured Convertible Debentures and 10,000,000 shares to certain service providers (see Note 4).



**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 4:-CONVERTIBLE DEBENTURE**

1. On April 3, 2006, the Company issued Senior Secured Convertible Debentures (the Debentures ), for gross proceeds of \$3,000,000. In conjunction with this financing, the Company issued 47,393,364 warrants exercisable for three years at an exercise price of \$0.075. The Company paid a finder's fee of 10% in cash and issued 9,478,672 warrants exercisable for three years, half of which are exercisable at \$0.075 and half of which are exercisable at \$0.077. The Company also issued 1,000,000 warrants in connection with the separate finder's fee agreement related to the issuance of the debenture exercisable for three years at an exercise price of \$0.075.

1a. The Debentures, which mature on April 3, 2008, are convertible to common shares at the lower of 75% of the volume weighted average trading price for the 20 days prior to issuance of a notice of conversion by a holder of a Debentures or, if while the Debentures remain outstanding the Company enters into one or more financing transactions involving the issuance of common stock or securities convertible or exercisable for common stock, the lowest transaction price for those new transactions.

Interest accrues on the Debentures at the rate of 7% per annum, is payable semi-annually on June 30 and December 31 of each year and on conversion and at the maturity date. Interest is payable, at the option of the Company, either (1) in cash, or (2) in shares of Common Stock at the then applicable conversion price. If the Company fails to deliver stock certificates upon the conversion of the Debentures at the specified time and in the specified manner, the Company will be required to make substantial payments to the holders of the Debentures.

1b. The Warrants, issued as of April 3, 2006, become first exercisable on the earlier of (i) the 65th day after issuance or (ii) the effective date of the Registration Statement. Holders of the Warrants are entitled to exercise their warrants on a cashless basis following the first anniversary of issuance if the Registration Statement is not in effect at the time of exercise.

The Company agreed to register the common shares issuable upon conversion of the Debentures and exercise of the warrants within 30 days after the Closing Date. The Registration Statement was filed and has declared effective as June 30, 2006.

Should the Registration cease to be effective during the time before the Convertible Debenture have matured, the Company will be required to pay substantial penalties to the holders of the Convertible Debenture.

Provided the Registration Statement is effective, the Company may prepay the amounts outstanding on the Debentures by giving advance notice and paying an amount equal to 120% of the sum of the principal being prepaid plus the accrued interest thereon. Holders will continue to have the right to convert their Debentures prior to the actual prepayment.

**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 4:-CONVERTIBLE DEBENTURE (CONT.)**

Holders of the Debentures may require the Company to redeem any or all of the outstanding Debentures upon the occurrence of any one or more of events of default specified in the Debentures.

Holders of Debentures are subject to certain limitations on their rights to convert the Debentures. The principal limitation is that the holder may not, with certain limited exceptions, convert into a number of shares that would, together with other shares held by the holder, exceed 4.99% of the then outstanding shares of the Company after such conversion. The exercise of the Warrants is subject to a similar limitation.

To secure the Company's obligations under the Debentures and other transaction agreements, the Company has granted a security interest in substantially all of its assets, including without limitation, its intellectual property, in favour of the investors under the terms and conditions of a Security Interest Agreement dated as of the date of the Debentures. The security interest terminates upon the earlier of (i) the date on which less than one-fourth of the original principal amount of the Debentures issued on the Closing Date are outstanding or (ii) payment or satisfaction of all of the Company's obligations under the Securities Purchase Agreement.

The conversion price of the Debentures and the exercise price of the Warrants are subject to adjustment. Under the agreements with the holders of the Debentures, the Company agreed that if the Company makes certain offers or sales of its Common Stock (or securities convertible into Common Stock) to any third party during the period from the Closing Date until the date that less than one-fourth of the aggregate principal amount of the Debentures issued remain unconverted, adjustments would be made to the conversion price of the then unconverted Debentures and to the exercise price of the then unexercised Warrants. The exercise price of the Warrants also are subject to adjustment in the event of certain capital adjustments or similar transactions, such as a stock split or merger. In addition, in certain cases, the investors may be entitled to receive additional warrants to purchase additional shares.

The Company also agreed that until less than one-fourth of the aggregate principal amount of the Debentures issued remain unconverted, without the prior written consent of more than 51% of the then outstanding Debentures, the Company will not enter into any new transaction for the offer or sale of the Company's securities when such transaction provides for a variable conversion price or a variable exercise price. The Company also agreed that until the effective date of the Registration Statement it will not enter into any other transaction for the offer or sale of any of its securities and, commencing on the effective date and for six months thereafter, the Company will not enter into any transaction granting the investors in that new transaction registration rights.

In accordance with EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to, and potentially settled in a Company's Own Stock" (EITF 00-19), the Company allocated the consideration paid for the convertible debenture and the warrants as follows:

**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 4:-CONVERTIBLE DEBENTURE (CONT.)**

The warrants were recorded as a liability based on their fair value in the amount of \$951,467. The Company estimated the fair value of the warrants using a Black and Scholes option pricing model, with the following assumptions: volatility of 83%, risk free interest rate of 4.8%, dividend yield of 0%, and an expected life of 36 months. Changes in the fair value are recorded as interest income or expense, as applicable.

The fair value of the conversion feature of the debentures, in the amount of \$1,951,466 was recorded as a liability.

The balance of the consideration, in the amount of \$97,067, was allocated to the debentures. The discount in the amount of \$2,902,933 was amortized according the effective rate interest method over the debentures contractual period (24 months).

The fair value of the warrants issued as finder's fee and the finder's fee in cash amounted to \$534,646 were recorded as deferred issuance expenses and are amortized over the debentures contractual period. The Company estimated the fair value of the warrants using a Black and Scholes option pricing model, with the following assumptions: volatility of 83%, risk free interest rate of 4.8%, dividend yield of 0%, and an expected life of 36 months.

The Company recorded in the six month and three month periods ended December 31, 2006 \$161,332 and \$47,693 respectively as financial expenses in respect to the discount amortization and accrued interest.

According to EITF 00-19, in order to classify warrants and options (other than employee stock options) as equity and not as liabilities, the Company should have sufficient authorized and unissued shares of common stock to provide for settlement of those instruments that may require share settlement. Under the terms of the convertible debentures dated April 3, 2006, the Company may be required to issue an unlimited number of shares to satisfy the debenture's contractual requirements. As such, on April 3, 2006, the Company's warrants and options (other than employee stock options) were classified as liabilities and measured at fair value with changes recognized currently in earnings. Till November 9, 2006 all of the Debentures were converted into 193,952,202 shares. As a result an amount of \$ 1,787,084 was reclassified into common stock and additional paid-in capital as follow: from conversion of the feature embedded in convertible debenture (\$1,951,466), convertible debenture (\$201,974) ,accrued interest (\$73,644) net of issuance expenses in the amount of \$440,000. In addition, the warrants and options to consultants in the amount of \$536,919 and deferred issuance expenses in the amount of \$378,708 were reclassified as equity.

Pursuant to an investor relation agreements dated April 28, 2006 and August 2006 the Company paid in cash an amount of \$440,000 on October 19, 2006 and issued 10,000,000 common shares on November 9, 2006 to certain service providers following reaching certain milestones regarding the conversion of the Convertible Debenture as agreed to by the parties.





**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 5:- SUBSEQUENT EVENTS**

Subsequent to the balance sheet date the Company received \$1,250,000 from private investors as down payment for straight equity investment.

###

F-31

---

**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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 are engaged in the business of the development of the Mesenchymal and stem cell production technology and the commercialisation of cell therapy products. We were incorporated in the State of Nevada under the name A.I. Software, Inc. on May 11, 2001. Beginning in 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. 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 production technology. This technology, if fully developed, 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 of which \$181,250 has been paid as of the balance sheet date and we will pay royalties on our future sales and product or rights distribution transactions. Also, the licensors of the license agreement have an option to assign all of their patent rights in the license agreement to our company in exchange for an aggregate of 5% of all of the issued and outstanding share capital of our company. This option may only be exercised within a 60-day period commencing from the date when we notify the licensors that the market capital of our company has exceeded \$25,000,000. The option will expire if it is not exercised within this period.

To enable us to conduct further research and development of the exclusive license for the stem cell production technology we acquired from the Weizmann Institute of Science and the Technion-Israel Institute of Technology, on June 10, 2003, 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 OTCBB at the opening of trading on June 30, 2003 under our new stock symbol PLRS.OB. From May 2003 until March 2006, our business has focussed on the development of the stem cell production technology that we license. Originally, our plan was to develop that technology to the point where we could sub-license it to medical scientists and practitioners for their use in producing cell therapy products for their own use for sale in the marketplace. On March 6, 2006, we announced that our company was taking a new direction. Now, instead of looking to sub-lease the stem cell production technology, we will focus on developing the technology with the goal of producing cell therapy products for sale in the marketplace.

On July 5, 2006, we announced that our subsidiary, Pluristem Ltd., achieved a breakthrough in our Preclinical Study of Bone Marrow Transplants: engrafted cells increased 2-4 times using Pluristem Ltd.'s innovative adjuvant cell therapy product known as PLX-I. PLX-I, by adding mesenchymal stromal cells during bone marrow transplant procedures that use umbilical cord blood samples, is intended to offer a breakthrough solution to improved engraftment of blood-producing hematopoietic stem cells.

#### *Our Current Business*

We are engaged in the business of the development of the stem cell production technology and the commercialisation of cell therapy products. We aim to become a leader in the production of stem cell based therapeutic products to improve the engraftment of hematopoietic stem cells in bone marrow transplants and growth or expansion of hematopoietic stem cells outside of the human body. Stem cells are unspecialised 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 production of stem cell based therapeutic products to improve the engraftment of hematopoietic stem cells in bone marrow transplants and expansion hematopoietic stem cells found in umbilical cord blood, using the technology platform we license pursuant to our 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 production system for the treatment of severe blood disorders. The first product targets a critical global shortfall of matched tissue for bone marrow transplantation. Pluristem Ltd started initial pre-clinical trials on mice that have insufficient immune systems so as to simulate human blood and immune systems (SCID mice) on PLX I our first cell therapy product. PLX I is developed as an Allogeneic product and is based on supplementing the umbilical cord blood cells with supportive cells that will improve the effectiveness of engraftments, shortening recovery time. The initial published animal study results show that sufficient engraftment is possible with the limited number of hemopoietic stem cells available in a single portion of umbilical cord blood. This paves the way towards using umbilical cord blood for cell engraftment instead of bone marrow transplants for adult patients.

We intend to test our first product in clinical trials to gain Federal Drug Administration approval.

#### **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 unspecialised 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 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



## Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

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 anemia,

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

### **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 anemia, 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



## Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

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 mononuclear 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;

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, two issues are critical for umbilical cord blood for cell engraftment to become an alternative to bone marrow transplants. The first issue is that there usually aren't enough blood-producing stem cells in the cord blood. The blood from an average baby's umbilical cord usually provides less than a third of the amount needed for the average adult patient. The second is late engraftment of the cord blood compared to a bone marrow transplant. The use of umbilical cord blood for adult patients is limited due to the small cell amount in each umbilical cord. The rate of donor hematopoietic reconstitution is lower and the time to engraftment is delayed using umbilical cord blood (30-40 days for neutrophils and platelets, dose and human leukocyte antigen match dependent) compared to bone marrow grafts (15-20 days for neutrophils and platelets, dose and human leukocyte antigen match dependent). This has prompted intensive research on *ex vivo* expansion of umbilical cord blood stem cells and umbilical cord blood graft technology that is able to improve umbilical cord





blood engraftment and reconstitution. Co-transplantation of human hematopoietic stem cells with bone marrow mesenchymal cells has been demonstrated to promote hematopoietic stem cell engraftment. Therefore, co-transplantation of mesenchymal stem cells derived from placenta together with umbilical cord blood may be considered as a promising manipulation for improvement of the hitherto delayed engraftment using cord blood as the source of stem cells.

To date, the small volume of blood collected from umbilical cords (typically less than 100 ml), use of umbilical cord blood has been limited to transplants in babies and children weighing less than 35 kg. Moreover, there are no existing hematopoietic stem cell production 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.

We are working to develop a solution to the late engraftment of the cord blood compared to a bone marrow transplant.

Pluristem has discovered and patented a technology process for growing and expanding mesenchymal stem cells and hematopoietic stem cells. PLX I mesenchymal stem cells has been proven to increase the umbilical cord blood stem cells effectiveness by 2-4 times in a pre-clinical study.

Mesenchymal cells are the founding cells of many tissues like bone, fat and cartilage and also enhance engraftment of hematopoietic stem cells following a bone marrow transplant. Hematopoietic stem cells are the founding cells of the hematopoietic system. They reside in the bone marrow and are mandatory for successful bone marrow transplants.

**PLX I** has been developed as an allogeneic product and is based on supplementing the umbilical cord blood cells with supportive cells that will improve the effectiveness of engraftments and shorten recovery times. After production, PLX I is stored ready to use. The patient does not have to wait several weeks for stem cells to grow in culture while his life is at risk. Once a matched cord blood is found, the PLX I is ready for use immediately on arrival at the hospital. PLX I is injected into the patient just a few hours before the cord blood injection to improve the engraftment. Additionally, it may be possible to boost engraftment of the hematopoietic stem cells by multiple potential injections.

Initial animal study results recently published show that sufficient engraftment is possible with the limited number of hematopoietic stem cells available in a single portion of umbilical cord blood. This paves the way towards using umbilical cord blood instead of bone marrow transplants for adult patients.

Pluristem derives and expands mesenchymal stem cells from human adult tissues (such as fat or placenta) and hematopoietic stem cells from umbilical cord blood. Umbilical cord blood is preferred over bone marrow as a source of hematopoietic stem cells for reasons of reduced fatalities of donors and increased efficiency to recipients. The cell expansion necessary to produce enough stem cells for a successful transplant is executed in an environment that mimics different naturally-occurring physiological environments. It does not include supplemented, potentially harmful growth factors and cytokines.

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 PLX I product would have the potential to change the way 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 production 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 production technology. This technology, if fully developed, may 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 production system that we can use to produce functional stem cells for sale to other research laboratories, umbilical cord blood banks, or clinics. We have named the technology 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 mimics 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 a similar 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 production of umbilical cord blood hematopoietic stem cells to proportions that will be enough for transplants in adults, without promoting differentiation.

We are designing and developing the PluriX Bioreactor system to perform controlled production 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.

**PLX II** is being developed as personalised product and is based on a co-culture of expanded autologous hematopoietic stem cells from cord blood and supporting tissue. The three dimensional stroma will be stored ready to use and when the expansion of hematopoietic stem cells from umbilical cord blood is needed, the stored cord blood will be cultivated on the stroma for 14 days in the PluriX bioreactor. After cultivation, the expanded hematopoietic stem cells will be separated from the stroma and the co-culture of the expanded hematopoietic stem cells and stroma cells will be injected.

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 transplants in adults. 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.

#### **Primary Advantages of PluriX Bioreactor System**

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

1. A proprietary bioreactor (PluriX ) system enables ex-vivo expansion of hematopoietic stem cells populations in a microenvironment resembling the architecture of natural bone marrow.
2. A unique micro-structure enables expansion of mesenchymal stem cells to very high densities.



3. Use of co-culture methodology provides a graft product containing both mesenchymal stem cells and hematopoietic stem cells. Transplantation of the co-culture graft allows for better engraftment of the hematopoietic stem cells in the recipient's bone marrow.
4. No use of exogenous biologics or pharmacologicals, eliminating the risk of genetic instability and allowing safer expansions of hematopoietic stem cells.
5. Use of cord blood mono-nuclear cells as the starter cohort for expansion, instead of immuno-selected subpopulations of hematopoietic stem cells, reduces regulatory constraints, increases expansion yields and decreases production costs.

#### *Markets for Our Product and Services*

We plan to produce and sell stem cell products for use in bone marrow transplants. 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, if we succeed in developing stem cells that will be compatible with more patients, as we are trying to do, we estimate that the number of potential bone marrow transplants in the United States and Europe would likely 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, standard bone marrow transplant procedure costs approximately \$100,000 per patient. 150,000 potential patients times \$100,000 per patient represent \$15 billion. This translates into approximately \$15 billion annually that patients and their medical insurers around the world may be spending. If we are successful in developing our technology and products so that donor searches and repeat procedures are reduced, the annual expenditures for bone marrow transplant procedures may decrease.

#### *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 products 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 covering a patent application entitled *Method and Apparatus for Maintenance and Production of Hematopoietic Stem Cells and/or Progenitor Cells* filed with the World Intellectual Property Organization under the Patent Cooperation Treaty (PCT) patent number PCT/US00/02688. Corresponding patent applications have also been filed in a number of countries including the United States under patent application number 09/890,401. On January 28, 2005, we received notice from the U.S. Patent and Trademark Office that it has allowed the U.S. patent application number 09/890,401, but changing the title of the patent from *Method and Apparatus for Maintenance and Production of Hemopoietic Stem Cells and/or Progenitor Cells* to *Method of Producing Undifferentiated Hemopoietic Stem Cells Using a Stationary Phase Plug-Flow Bioreactor*. This patent allowance - No 6,911,201 provides coverage to our concept of creating a three-dimensional bone-like environment that supports stem cell production without differentiation.

Our other issued patents were issued in South Africa (patent #2001/6486), Australia (patent #759719) Russia (patent #2249039) and New Zealand (patent #513303) between the years 2002 and 2005. These patents are due to expire in the years 2022 to 2025. These patents present claims to: (i) certain apparatus for cell culturing, including a bioreactor suitable for culturing human hematopoietic stem cells or hematopoietic progenitor cells; (ii) three dimensional stromal cells based bioreactor. In addition, we plan to file applications, either alone or in conjunction with our exclusive licensors, for patents in the United States and equivalent applications in certain other countries claiming other aspects of our technology, products and processes.

The validity and breadth of claims in medical technology and products 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 products 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 are issued, we also can not 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 agreement, 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. For complete details regarding our license, please see the license agreement itself, which is incorporated by reference as an exhibit to this periodic report.

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 develop our technology and commercialise cell therapy products 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 develop our technology or maintain our competitive position with respect to our potential cell therapy products. 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 or products. 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 products 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 of our technology and the commercialisation our potential cell therapy products.

Pluristem Life Systems Inc. filed one provisional patent with the US Patent and Trademark Office for a new procedure for expanding hematopoietic stem cells and early progenitor cells from cord blood from non selected mono-nuclear cells of the cord blood.

The methodologies used in current hematopoietic stem cells expansion protocols apply a selection stage before the enrichment stage where the input cell population is defined by the expression of a cell membrane marker CD34. This is a rare subpopulation of cells that are selected from large and mixed populations of mono-nuclear cells.

The selection process is associated with several drawbacks. First, it causes a substantial loss of source cells. Second and most importantly, the selected population of cells may not represent the earliest extractable population of hematopoietic stem cells. Pluristem's expansion protocol is intended to overcome both hurdles by using cord blood from non-selected mono-nuclear cells to fuel the enrichment process.

This approach allows Pluristem to independently utilize two already patent protected processes: the selection of CD34 cells and use of proprietary manufactured cytokines.





Pluristem's advanced method for expanding target hematopoietic stem cells population from cord blood is a two-fold approach. First, a state-of-the-art patented bioreactor mimicking the natural bone marrow environment is used. Second, mono-nuclear cells rather than CD34 selected cells are targeted as the starting source of hematopoietic stem cells. The efficacy of the expansion process that utilizes non-selected mono-nuclear cells of the cord blood is superior to what is currently being achieved by using CD34 selected cells as the starting population of cells.

In May, 2006, our subsidiary, Pluristem Ltd., filed an application for a provisional patent with the US Patent and Trademark Office for its stem cell therapy product known as PLX-I. PLX-I is intended to offer a breakthrough solution to improved engraftment during bone marrow transplant procedures that use umbilical cord blood.

PLX-I, which consists of propagated mesenchymal stem cells that can be co-transplanted along with the hematopoietic stem cells, is expected to significantly improve the engraftment rate of the hematopoietic stem cells.

The role of PLX-I is to improve the homing of hematopoietic stem cells and their lodgment into the patient hematopoietic niche using mesenchymal cells. This new technology is based on Pluristem's ex vivo expanded mesenchymal cells that are expanded within the proprietary PluriXTM high density 3-D cultures system.

The mesenchymal cells are expanded to achieve the quality and amount required for improving hematopoietic stem cells and progenitor cell repopulation, and to enhance bone marrow engraftment following stem cell transplantation.

#### *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 production 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 placenta tissues 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.



Stromal cells Culture Development & Optimization - At this stage we intend to focus on the establishment of Master bank of stromal cells cultured on 3D carriers. maintenance of stromal cells on 3D carriers and testing of expanded stromal cells outside a host body using mice without immune systems repopulating cells assay.

Regulatory Approval - We intend to prepare and file with the Food and Drug Administration and other relevant health authorities an Investigational New Drug or an Investigational application to initiate human clinical trials designed to demonstrate the safety, efficacy and clinical benefits of PLX I cells. We intend to carry out all research and development activities with the advice of a Food and Drug Administration advisor.

#### *Employees*

We presently have 12 full time employees and 2 part time employees in research and development and 4 full time employees and 1 part time employee in management through our wholly owned subsidiary, Pluristem, Ltd.

#### *Competition*

The biotechnology and medical device industries are characterised 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 commercialisation of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organisations are also conducting research activities and seeking patent protection and may commercialise 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 and our potential products obsolete or non-competitive, that we will be able to keep pace with new technological developments or that our potential products 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 and products are 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 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 use, and our potential products, 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: Osiris Therapeutics, Inc., Aastrom Biosciences, Inc., ViaCell Inc., Gamida-Cell Ltd., Advanced Cell Technology, Inc., BioTransplant Inc., StemCell Technologies, Inc. and CellGenix. However, to the best of our knowledge none of these companies have developed a platform that can support production of hematopoietic stem cells without promoting their differentiation in cytokines free conditions.

#### *Government Regulations and Supervision*

Once fully developed, we intend to market our stem cells to research laboratories, clinics and umbilical blood banks primarily in the United States and in Europe. Accordingly, we believe our research and development of our technology and the production and marketing of our stem cells are subject to the laws and regulations of governmental authorities in the United States and all other countries where our technology will be used and our stem cells 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.



## **The Regulatory Process**

In the United States and in Europe, regulatory approval of new medical devices and biological products involves a lengthy process 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 may develop our PluriX Bioreactor system into a GMP-compliant cell culture system for production of human cells outside of the human body for therapeutic applications. GMP is a standard set for laboratories by the World Health Organization and other health regulatory authorities. Therefore, to a certain degree, the manner in which the Food and Drug Administration will regulate our PluriX Bioreactor system is uncertain.

We understand that the Food and Drug Administration is still in the process of developing its requirements with respect to somatic cell therapy and gene cell therapy products and has issued draft documents concerning the regulation of cellular and tissue-based products. If the Food and Drug Administration adopts the regulatory approach set forth in the draft document, the Food and Drug Administration will require 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 stem cells produced by our PluriX Bioreactor system are 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, which may include our future clinics, 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, labeling, storage, record-keeping, approval, distribution, use, reporting, advertising and promotion of our future products. Noncompliance 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 in the United States**

We are currently only in the developmental stage of our technology, PluriX Bioreactor system and potential products and have not begun the process of seeking regulatory approval from the Food and Drug Administration. Once our PluriX Bioreactor system is fully developed, we intend to consult with a Food and Drug Administration advisor to assist us in determining our path in the process toward gaining regulatory approval from the Food and Drug Administration. Obtaining regulatory approval of new medical devices and 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 and potential products 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.

Where human clinical trials of a proposed medical product are required, the manufacturer or distributor of the product will have to file an Investigational Device Exemption or 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 Food and Drug Administration categorizes medical devices into three regulatory classifications subject to varying degrees of regulatory control. In general, Class I devices require compliance with labeling and record keeping regulations, Quality System Regulation, 510(k) pre-market notification, and are subject to other general controls. Class II devices may be subject to additional regulatory controls, including performance standards and other special controls, such as post-market surveillance. Class III devices, which are either invasive or life-sustaining products, or new products never before marketed (for example, non-substantially equivalent devices), require clinical testing to demonstrate safety and effectiveness and the approval of the Food and Drug Administration prior to marketing and distribution.

We believe that our PluriX Bioreactor system, if successfully developed, will be classified as a Class III medical device and be subject to the requirements of clinical testing to demonstrate safety and efficacy and the approval of the Food and Drug Administration before we can market the stem cells.

In addition, we, and any contract manufacturer, may be required to be registered as a medical device manufacturer with the Food and Drug Administration. These manufacturers will be inspected on a routine basis by the Food and Drug Administration 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 Medical Device Reporting regulation requires that we provide information to the Food and Drug Administration on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. In addition, the Food and Drug Administration prohibits a company from promoting an approved device for unapproved applications and reviews company labeling for accuracy.

Also, if we are able to successfully develop our PluriX Bioreactor system, we believe that the stem cells produced in the PluriX Bioreactor system 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 Device Exemption or Investigational Device Exemption New Drug application 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 Device Exemption. Following the submission of an Investigational Device 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 affects be reported to the Food and Drug Administration and may also require post-marketing testing to monitor for adverse affects, 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 Device 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. If we are successful in developing our technology and obtaining regulatory approval to the point where we are ready to produce stem cells for sale, our laboratories where we will produce those cells will be subject to all Food and Drug Administration licensing, registration and inspection requirements.

### **Product Approval in Europe**

If we successfully develop our PluriX bioreactor system and potential cell therapy products and seek regulatory approval in Europe, we believe our PluriX Bioreactor system may be regulated in Europe as a Class I Sterile, Class IIb or Class III medical device, under the authority of the Medical Device Directives being implemented by European Union member countries. These classifications apply to medical laboratory equipment and supplies including, among other products, many devices that are used for the collection and processing of blood for patient therapy.

The applicable regulations vest the authority to permit affixing of the CE Mark with various notified bodies. These are private and state organisations which operate under license from the member states of the European Union to certify that appropriate quality assurance standards and compliance procedures are followed by developers and manufacturers of medical device products or, alternatively, that a manufactured medical product meets a more limited set of requirements. Notified bodies are also given the responsibility for determination of the appropriate standards to apply to a medical product. Receipt of permission to affix the CE Mark enables a company to sell a medical device or product in all European Union member countries. Other registration requirements may also need to be satisfied in certain countries. We have not received permission from a notified body to affix the CE Mark to our PluriX Bioreactor system, nor have we as yet requested such permission.

## PLAN OF OPERATIONS

### *Overview*

You should read the following discussion of our financial condition and results of operations together with the unaudited financial statements and the notes to unaudited financial statements included elsewhere in this filing prepared in accordance with accounting principles generally accepted in the United States. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those anticipated in these forward-looking statements.

We are engaged in the business of the development of the Mesenchymal and stem cell production technology and the commercialisation of cell therapy products. 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 production technology. This technology, if fully developed and commercialised, 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.

From May 2003 until March 2006, our business has focussed on the development of the stem cell production technology that we license. Originally, our plan was to develop that technology to the point where we could sub-license it to medical scientists and practitioners for their use in producing cell therapy products for their own use for sale in the marketplace. On March 6, 2006, we announced that our company was taking a new direction. Now, instead of looking to sub-lease the stem cell production technology, we will focus on developing the technology with the goal of producing cell therapy products for sale in the marketplace.

Under our licensing agreement, we agreed to pay \$400,000 cash over time of which \$181,250 has been paid as of the balance sheet date and we may pay royalties on our future sales and product or rights distribution transactions. Also, the licensors of the license agreement have an option to assign all of their patent rights in the license agreement to our company in exchange for an aggregate of 5% of all of the issued and outstanding share capital of our company. This option may only be exercised within a 60-day period commencing from the date when we notify the licensors that the market capital of our company has exceeded \$25,000,000. The option will expire if it is not exercised within this period.

To enable us to conduct further research and development of the exclusive license for the stem cell production technology we acquired from the Weizmann Institute of Science and the Technion-Israel Institute of Technology, on June 10, 2003, 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.

### *Plan of Operations*

You should read the following discussion of our financial condition and results of operations together with the unaudited financial statements and the notes to unaudited financial statements included elsewhere in this filing prepared in accordance with accounting principles generally accepted in the United States. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those anticipated in these forward-looking statements.

#### Research and Development Costs

For the next twelve months, we estimate that our research and development costs will be approximately \$1,750,000. We intend to spend our research and development costs on optimizing the 3-D bioreactor operations, developing the expanded hematopoietic stem cell product, developing the expanded of our Placenta Mesenchymal stem cell product, implanting stem cells from cord blood into the stromal cell cultures of PluriX Bioreactors for production and conducting studies on mice to examine stem cell development and production.



#### General and Administrative Expenses

For the next twelve months, we estimate that our general and administrative expenses will be approximately \$1,500,000. These expenses will include management services, public relations and investor relations and additional amounts on 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 from sales of products in the next twelve months. We may generate revenues from sale of License to use our technology. Our products will likely not be ready for sale for at least five years, if at all.

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

Optimize 3-D PluriX™ Bioreactor operations We have made progress using the 3-D environment of the PluriX™ to produce a dense population of stromal supporting cells that provide a basis for stem cell in vitro production without differentiation. However, to have a potential product that we might eventually be able to market, we must continue to try to develop the bioreactor system until it can produce stem cells that will self-renew while remaining in their original state;

Improve the analytical methods of our technology and processes;

Conduct studies to analyze the hematopoietic stem cell to reconstitute the hematopoietic system within animal model. Trials are planned using SCID mice which are mice with insufficient immune systems that can be used to simulate human blood and immune systems. Using this model, the human hematopoietic stem cell may develop and differentiate Pluristem's in vitro production process to be analyzed in vivo. Clarify and finalize our regulatory and medical strategy for meeting with the Food and Drug Administration.

Establish relations with research centers and cord blood banks.

#### *Liquidity and Capital Resources*

During the three month period ended December 31, 2006, we incurred a net loss of \$682,179, as compared to a net loss of \$486,017 in the three month period ended December 31, 2005. This resulted from moving forward with our research and development plan. We obtained funds to carry on our business from private placements we conducted in October of 2004 and January of 2005, which raised gross proceeds of approximately \$3,250,000 through the issuance of 32,500,000 units comprising one common share and one common share purchase warrants. On April 3, 2006 we raised gross proceeds of approximately \$3,000,000 through the issuance of senior secured convertible debentures. As at December 31, 2006 we had cash of \$842,880 and subsequent to the balance sheet date we have received \$1,250,000 from private investors as down payment for straight equity investment which is sufficient to fund our operations for until early summer.

While we expect that we have sufficient funds to operate until early summer of 2007, we will have to raise additional funds from the market before we have any cash flow from operations. We believe that it will take several years for us to complete the approval process for our products in the United States or any other jurisdiction. In addition, future decisions regarding any acquisitions that we may choose to make or product development that is beyond the scope of what is described in our Plan of Operations will require additional capital, which must be raised through the issuance additional securities and/or incurring more debt.

#### *Research and Development*

Since June 10, 2003, the date we acquired Pluristem, Ltd., 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 the remainder of 2007, we will continue with the research and development activities referenced above. Since inception



## Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

to December 31, 2006, we have spent \$4,637,350 on research and development. We hope that eventually, all of this cost will be passed on to our customers.

### *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 will upgrade our facilities to GMP like facilities and we will spend about \$500,000 on equipment that we will need to conduct our planned research and development and manufacturing for the next twelve months.

### *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, 2006, 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 shareholders. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments.

### *Recently Issued Accounting Standards*

#### FASB Interpretation No. 48:

In July 2006, the FASB issued FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 utilizes a two-step approach for evaluating tax positions. Recognition (step one) occurs when an enterprise concludes that a tax position, based solely on its technical merits, is more-likely-than-not to be sustained upon examination. Measurement (step two) is only addressed if step one has been satisfied (i.e., the position is more-likely-than-not to be sustained). Under step two, the tax benefit is measured as the largest amount of benefit, determined on a cumulative probability basis that is more-likely-than-not to be realized upon ultimate settlement.

FIN 48 applies to all tax positions related to income taxes subject to the Financial Accounting Standard Board Statement No. 109, "Accounting for income taxes" ("FAS 109"). This includes tax positions considered to be "routine" as well as those with a high degree of uncertainty.

FIN 48 has expanded disclosure requirements, which include a tabular roll forward of the beginning and ending aggregate unrecognized tax benefits as well as specific detail related to tax uncertainties for which it is reasonably possible the amount of unrecognized tax benefit will significantly increase or decrease within twelve months. These disclosures are required at each annual reporting period unless a significant change occurs in an interim period.

FIN 48 is effective for fiscal years beginning after December 15, 2006. The cumulative effect of applying FIN 48 will be reported as an adjustment to the opening balance of retained earnings. The Company does not expect that the adoption of FIN 48 will have a significant impact on the Company's financial position and results of operations.

#### SFAS No. 157:

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("SFAS No. 157"). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations. The statement does not apply to accounting standard that require or permit measurement similar to fair value but are not intended to represent fair value. This pronouncement is effective for





## Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of adopting SFAS 157.

Staff Accounting Bulletin No. 108:

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108") Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, that provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. This pronouncement is effective for fiscal years ending after November 15, 2006. The Company is currently evaluating the provisions of SAB 108.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108") Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, that provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. This pronouncement is effective for fiscal years ending after November 15, 2006. The Company is currently evaluating the provisions of SAB 108.

### **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.

#### *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 \$8,055,320 since inception through the six month period ended December 31, 2006.

#### *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 21, 2006.

### **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 commercialising stem cell production 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 commercialising stem cell production 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 production 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 production 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 our stem cell production technology and commercialise our cell therapy products. 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 have a going concern note as described in an explanatory paragraph to our consolidated financial statements for the year ended June 30, 2006.

*Our likelihood of profit depends on our ability to develop and commercialise products based on our stem cell production technology, which is currently in the development stage. If we are unable to complete the development and commercialisation of our stem cell products successfully, our likelihood of profit will be limited severely.*

We are engaged in the business of developing and commercialising products based on a technology and proposed device called the PluriX Bioreactor system. 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 be used in bone marrow transplants and other methods of cell therapy. Our PluriX Bioreactor system and our products are in the development stage and we have not begun the regulatory approval process. 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 commercialisation of our potential cell therapy products, 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 our potential cell therapy products, 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 our cell therapy products 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 and our potential cell therapy products 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 commercialisation 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 our products 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 gross proceeds of approximately \$3,000,000 through issuing a senior convertible debenture on April 3, 2006 to support the development and commercialisation of our PluriX Bioreactor system and our potential cell therapy products. The funds from this financing are expected to fund operations until early summer of 2007. Our ability to continue to develop the PluriX Bioreactor system and commercialise our potential cell therapy products is dependent upon our ability to raise significant additional financing when needed. If we are unable to obtain such financing, we will not be able to fully develop our technology and commercialise our cell therapy products. 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 commercialisation 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 stockholders. 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, jeopardising 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 of our PluriX Bioreactor system and commercialisation of our potential cell therapy products, 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 our potential cell therapy products, our ability to commercialise our potential cell therapy products will be limited severely.*

Once our PluriX Bioreactor system and our potential cell therapy products are fully developed, we intend to market our potential cell therapy products primarily in the United States, Europe and Japan. We must obtain the approval of the Food and Drug Administration of our technology and potential cell therapy products before commercialisation of our potential cell therapy products may commence in the United States and similar agencies 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, 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 and our potential products.

Furthermore, even if we obtain regulatory approval for our PluriX Bioreactor system and our potential cell therapy products, that approval may be subject to limitations on the indicated uses for which they 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 and our potential cell therapy products.

*Even if we obtain regulatory approvals to commercialise our cell therapy products, we may encounter a lack of commercial acceptance of our cell therapy products, which would impair the profitability of our business.*

Our research and development efforts are primarily directed toward obtaining regulatory approval for our PluriX Bioreactor system and our potential cell therapy products. We intend that our potential products be used as an alternative or improvement to the cells currently harvested and used in bone marrow transplants. Current methods of stem cell collection and use have been widely practised for a number of years, and our technology and products may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, our PluriX Bioreactor system and products 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 our potential cell therapy products 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 and products may become obsolete and our business may suffer.*

The market for our products 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 products, including some by private companies from 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 products. Our competitors may have developed, or could in the future develop, new products that compete with our products or even render our products 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 products and we will suffer a competitive disadvantage. Finally, to the extent that others develop new products that address the targeted application for our products, 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. 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 and our cell therapy products. If our patents and proprietary right agreements do not provide sufficient protection for our PluriX Bioreactor system technology and our cell therapy products, 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. We also intend to seek patent protection for any of our potential cell therapy products once we have completed their development. 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 our technology and commercially viable products 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 our PluriX Bioreactor system and market our potential cell therapy products 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 marketing our potential cell therapy products 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 commercialisation 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 our products 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 neighbours 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 Defence 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 42 and 54 years old, depending upon the nature of their military service.

*We will be subject to the requirement that of Section 404 of the Sarbanes-Oxley Act in the future. If we will be unable to comply with the requirement in a timely manner the market price of our stock could decline*

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in 2008, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

*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 you 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.





*Our stock is considered a penny stock and certain securities rules may hamper the tradability of our shares in the market.*

Shares of our common stock are subject to rules adopted by the Securities and Exchange Commission that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stock is defined to be any equity security that has a market price (as defined) less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. Our common stock are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and accredited investors. The term accredited investor refers generally to institutions with assets in excess of \$5,000,000 or individuals with a net worth in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardised risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities.

### **Item 3. Controls and Procedures.**

As required by Rule 13a-15 under the Exchange Act, as of the end of the period covered by this report, being December 31, 2006, we have carried out an evaluation of the effectiveness of the design and operation of our company's disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based upon that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report. There have been no changes in our internal controls over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

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 reports filed under the Exchange Act is accumulated and communicated to management, including our 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**

None.



**Item 3. Defaults Upon Senior Securities.**

None.

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

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

*Exhibits required by Item 601 of Regulation S-B*

**(3) Articles of Incorporation and 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).

3.4 Amended Bylaws (incorporated by reference from our Current Report on Form 8-K filed January 22, 2007).

**(10) Material Contracts**

10.1 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).

10.2 Form of Common Stock and Warrant Purchase Agreement between our company and each of the following investors who participated in the October 25, 2004 Private Placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).

10.3 Form of Warrants between our company and each of the following investors who participated in the October 25, 2004 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).

10.4 Form of Agents Warrants between our company and each of the following agents who participated in the October 25, 2004 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).

## Edgar Filing: PLURISTEM LIFE SYSTEMS INC - Form 10QSB

- 10.5 Form of Common Stock and Warrant Purchase Agreement between our company and each of the investors who participated in the January 24, 2005 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).
- 10.6 Form of Warrants between our company and each of the following investors who participated in the January 24, 2005 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).
- 10.7 Form of Agents Warrants between our company and each of the following agents who participated in the January 24, 2005 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).

- 10.8 Form of Warrants between our company and each of the following investors who participated in the January 31, 2005 private placement (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).
- 10.9 Agent s Warrant for 600,000 warrants between our company and Yokim Asset Management Corp. in respect of the January 31, 2005 private placement. (incorporated by reference from our registration statement on Form SB-2 filed April 27, 2005).
- 10.10 Form of Securities Purchase Agreement between our company and each of the investors who participated in the April 3, 2006 senior secured convertible debenture private placement (incorporated by reference from our 8-K filed April 3, 2006).
- 10.11 Form of Debenture between our company and each of the investors who participated in the April 3, 2006 senior secured convertible debenture private placement (incorporated by reference from our 8-K filed April 3, 2006).
- 10.12 Form of Warrants between our company and each of the investors who participated in the April 3, 2006 senior secured convertible debenture private placement (incorporated by reference from our 8-K filed April 3, 2006).
- 10.13 Form of Registration Rights Agreement between our company and each of the investors who participated in the April 3, 2006 senior secured convertible debenture private placement (incorporated by reference from our 8-K filed April 3, 2006).
- 10.14 Form of Security Interest Agreement between our company and each of the investors who participated in the April 3, 2006 senior secured convertible debenture private placement (incorporated by reference from our 8-K filed April 3, 2006).

**(21) Subsidiaries**

Pluristem, Ltd., an Israeli company.

**(31) Rule 13a-14(a)/15d-14(a) Certifications**

31.1\* Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Zami Aberman

31.2\* Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Yaky Yanay

**(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/ Zami Aberman

Zami Aberman, Chief Executive Officer

(Principal Executive Officer)

Date: February 13, 2007

By: /s/ Yaky Yanay

Yaky Yanay, Chief Accounting Officer

(Principal Financial Officer and Principal Accounting Officer)

Date: February 13, 2007