

HEPALIFE TECHNOLOGIES INC  
Form 10QSB  
May 13, 2004

**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 quarterly period ended March 31, 2004**

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

**HEPALIFE TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

**Florida**

(State or other jurisdiction of incorporation)

**000-29819**

(Commission File Number)

**58-2349413**

(I.R.S. Employer Identification No.)

**1628 West 1st Avenue, Suite 216, Vancouver, British Columbia, V6J 1G1**

(Address of principal executive offices)

**(800) 518-4879**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 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

State the number of shares outstanding of each of the Issuer's classes of common equity as of the latest practicable date. As of April 28, 2004, there were 64,390,832 shares of the Issuer's Common Stock, \$0.001 par value per share outstanding.

Transitional Small Business Disclosure Format (Check One): Yes [ ] No [X]

**TABLE OF CONTENTS**

**HEPALIFE TECHNOLOGIES, INC.**

**FORM 10-QSB, QUARTER ENDED MARCH 31, 2004**

**PART I FINANCIAL INFORMATION**

Item 1. Financial Statements

Interim Unaudited Balance Sheet

3

Interim Unaudited Statements of Operations

4

Interim Unaudited Statements of Cash Flows

5

Notes to Interim Financial Statements

6

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

8

Item 3. Controls and Procedures

20

## **PART II OTHER INFORMATION**

Item 1. Legal Proceedings

21

Item 2. Changes in Securities and Use of Proceeds

21

Item 3. Defaults Upon Senior Securities

21

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

21

Item 5. Other Information

21

Item 6. Exhibits and Reports on Form 8-K

21

Signatures

22

Certifications

23

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**PART I FINANCIAL INFORMATION**

**HEPALIFE TECHNOLOGIES, INC.**

**(formerly known as ZETA CORPORATION)**

**(A Development Stage Company)**

**INTERIM BALANCE SHEET**

**MARCH 31, 2004**

**(Unaudited)**

**ASSETS**

Current Assets

Cash	<u>\$381,461</u>
Total Current Assets	<u>381,461</u>

Total Assets \$381,461

**LIABILITIES AND STOCKHOLDERS' EQUITY  
(DEFICIENCY)**

Current Liabilities

Accounts Payable and Accrued Liabilities, Related Party	<u>\$80,934</u>
Notes Payable, Related Party, Unsecured	<u>725,000</u>
Total Current Liabilities	<u>805,934</u>

Stockholders' Equity (Deficiency)

Preferred Stock: \$0.10 Par Value; Authorized Shares,  1,000,000 shares; Issued and Outstanding, None	None
Common Stock: \$0.001 Par Value; Authorized Shares,  300,000,000; Issued and Outstanding, 64,390,832 Shares	64,391
Additional Paid In Capital	1,919,459
Loss Accumulated During the Development Stage	<u>(2,408,323)</u>
Total Stockholders' Equity (Deficiency)	<u>(424,473)</u>
 Total Liabilities and Stockholders' Equity (Deficiency)	 <u>\$381,461</u>

See condensed notes to financial statements.

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**HEPALIFE TECHNOLOGIES, INC.**  
**(formerly known as ZETA CORPORATION)**  
**(A Development Stage Company)**

**INTERIM STATEMENTS OF OPERATIONS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003,  
AND FROM INCEPTION (OCTOBER 21, 1997) TO MARCH 31, 2004**

**(Unaudited)**

	For the Three Months Ended <u>March 31, 2004</u>	For the Three Months Ended <u>March 31, 2003</u>	From Inception (October 21, 1997) to <u>March 31, 2004</u>
Revenues	\$0	\$0	\$0
Expenses			
General and Administrative			
(Related Party-2004:\$12,875 and 2003:\$9,000)	76,016	13,455	2,285,689
Research and Development	20,700	0	153,600
Other Income			
Interest Income	552	70	30,966
Provision for Income Taxes	=	=	=
Net Loss Available to Common Stockholders	<u>\$(96,164)</u>	<u>\$(13,385)</u>	<u>\$(2,408,323)</u>
Basic and Diluted Loss Per Common Share	<u>\$(0.002)</u>	<u>\$(0.000)</u>	
Weighted Average Common Shares Outstanding	<u>64,214,332</u>	<u>56,613,332</u>	

See condensed notes to financial statements.

**HEPALIFE TECHNOLOGIES, INC.**

**(formerly known as ZETA CORPORATION)**

**(A Development Stage Company)**

**INTERIM STATEMENTS OF CASH FLOWS**

**FOR THE THREE MONTHS ENDED MARCH 31, 2004 AND 2003, AND  
FOR THE PERIOD FROM INCEPTION (OCTOBER 21, 1997) TO MARCH 31, 2004**

**(Unaudited)**

	Three Months Ended <u>March 31, 2004</u>	Three Months Ended <u>March 31, 2003</u>	From Inception (October 21, 1997) to <u>March</u> <u>31, 2004</u>
Cash Flows From Operating Activities			
Net Loss	\$(96,164)	\$(13,385)	\$ (2,408,323)
Adjustments to Reconcile Net Loss to Net Cash Used			
In Operating Activities			
Common Stock Issued For Services	-	-	523,100
Depreciation	-	288	3,471
Conversion of Debt to Equity			338,000
Changes in Assets and Liabilities			
Increase (Decrease) in Accounts Payable	(1,226)	6,600	80,933
Total Adjustments	(1,226)	6,888	945,504
Net Cash Flows Used In Operating Activities	(97,390)	(6,497)	(1,462,819)
Cash Flows From Investing Activities			



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Purchase of Property and Equipment	-	-	(3,471)
Net Cash Flows Used In Investing Activities	0	0	(3,471)
Cash Flows From Financing Activities			
Proceed From Notes Payable		-	725,000
Proceed From Issuance of Common Stock	166,650	-	1,122,750
Net Cash Flows Provided By Financing Activities	166,650	0	1,847,750
Increase (Decrease) in Cash and Cash Equivalents	69,260	(6,497)	381,461
Cash and Cash Equivalents, Beginning of Period	312,201	28,602	-
Cash and Cash Equivalents, End of Period	<u>\$381,461</u>	<u>\$22,105</u>	<u>\$381,461</u>

Supplemental Information

Cash paid for:

Interest and Income Taxes	\$0	\$0	\$0
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Noncash investing and financing activities:

Conversion of debt to equity	\$0	\$0	\$338,000
Common Stock Issued For Services	\$0	\$0	\$523,100

See condensed notes to financial statements.

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**HEPALIFE TECHNOLOGIES, INC.**

**(formerly known as ZETA CORPORATION)**

**(A Development Stage Company)**

**NOTES TO FINANCIAL STATEMENTS**

**MARCH 31, 2004**

NOTE 1. STATEMENT OF INFORMATION FURNISHED

The accompanying unaudited interim financial statements have been prepared in accordance with Form 10-QSB instructions and in the opinion of management contains all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position as of March 31, 2004, and the results of operations and cash flows for the three months ended March 31, 2004 and 2003. These results have been determined on the basis of generally accepted accounting principles and practices in the United States and applied consistently with those used in the preparation of the Company's 2003 Annual Report on Form 10-KSB.

Certain information and footnote disclosure normally included in the financial statements presented in accordance with generally accepted accounting principles in the United States have been condensed or omitted. It is suggested that the accompanying financial statements be read in conjunction with the accompanying financial statements and notes thereto incorporated by reference in the Company's 2003 Annual Report on Form 10-KSB.

NOTE 2. EARNINGS (LOSS) PER SHARE

Basic earnings or loss per share is based on the weighted average number of common shares outstanding. Diluted earnings or loss per share is based on the weighted average number of common shares outstanding and dilutive common stock equivalents. The computation of earnings (loss) per share is net loss available to common stockholders (numerator) divided by the weighted average number of common shares outstanding (denominator). All earnings or loss per share amounts in the financial statements are basic earnings or loss per share, as defined by SFAS No. 128, Earnings Per Share. Diluted earnings or loss per share does not differ materially from basic earnings or loss per share for all periods presented. Convertible securities that could potentially dilute basic earnings or loss per share in the future are not included in the computation of diluted earnings or loss per share because to do so would be antidilutive. All per share and per share information are adjusted retroactively to reflect stock splits and changes in par value.

The computation of basic and diluted loss per share is as follows:

Three months ended	Three months ended	Inception (October 21, 1997) to
March 31, 2004	March 31,	March 31, 2004

2003

Numerator-net loss available to common stockholders	\$ (96,164)	\$ (13,385)	\$ (2,408,323)
Denominator-weighted average number of common shares outstanding	64,214,332	56,613,332	
Basic and diluted loss per common share	\$ (0.002)	\$ (0.000)	

NOTE 3 - GOING CONCERN

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplates continuation of the Company as a going concern. However, the Company has sustained substantial operating losses in recent years resulting in a substantial accumulated deficit. In view of these matters, realization of a major portion of the assets in the accompanying balance sheet is dependent upon the continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements, and the success of its future operations.

To meet these objectives, the Company plans to seek additional equity and expects to raise funds through private or public equity investments in order to support existing operations and expand the range and scope of its business. There is no assurance that such additional funds will be available for the Company on acceptable terms, if at all. Management believes that actions presently taken to revise the Company's operating and financial requirements provide the opportunity for the Company to continue as a going concern. The Company's ability to achieve these objectives cannot be determined at this time.

NOTE 4 - RELATED PARTY TRANSACTIONS

**Management Fees:** During the three months ended March 31, 2004 and 2003, the Company charged \$0 and \$9,000, respectively, to operations for management and consulting fees incurred for services rendered by Mr. Harmel S. Rayat, a Director, Secretary/Treasurer and majority shareholder of the Company. As of March 31, 2004, the Company owed \$27,000 for outstanding management fees, which is included in accounts payable and accrued liabilities. There is no management or consulting agreement in effect nor is there an agreement in place to convert debt to equity, which is done at the discretion of Mr. Rayat and upon approval by the board of directors.

**Notes Payable and Accrued Interest:** Notes payable totally \$725,000 as at March 31, 2004, represents unsecured loans of \$300,000 (due on May 29, 2004 and bearing an interest rate of 7.25%), \$350,000 (due on August 28, 2004 and bearing an interest rate of 7.00%) and \$75,000 (due on November 19, 2004 and bearing an interest rate of 7.00%) due to Mr. Harmel S. Rayat, a Director, Secretary/Treasurer and majority shareholder of the Company. Accrued and

unpaid interest on these notes during the three month period ended March 31, 2004, amounted to \$12,875.

Property: The Company's principal office is located at 1628 West First Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. These premises are owned by a private corporation controlled by a director and majority shareholder of the Company. At present, HepaLife pays no rent and we believe that the existing facilities are adequate to meet our requirements for the near term. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

#### NOTE 5 COOPERATIVE AGREEMENT

On November 1st, 2002, the Company entered into a Cooperative Research and Development Agreement (the agreement) with the United States Department of Agriculture's (USDA) Agricultural Research Service (ARS), and committed a total payment of \$292,727 to ARS over two year period, as listed below:

(1) \$91,500 within 30 days of signing the Agreement; (paid in 2002)

(2) \$20,700 on or before 8/19/03; (paid 2003)

(3) \$20,700 on or before 11/19/03; (paid 2003)

(4) \$20,700 on or before 2/19/04; (paid 2004)

(5) \$91,500 on or before 5/19/04;

(6) \$15,875 on or before 8/19/04;

(7) \$15,876 on or before 11/19/04; and

(8) \$15,876 on or before 2/19/05

The agreement is for the purpose of funding salaries, equipment, travel and other indirect costs of a post-doctoral research associate. The terms of the agreement require the interaction of the Company with ARS personnel on the technical details involved with pig liver cell culture development, providing the necessary funds for the purpose above, preparing and filing any patent applications, and reviewing reports and implementing procedures for the development of an artificial liver device utilizing the pig liver cell line. ARS's responsibilities include hiring the post-doctoral research associate for a two-year period, providing laboratory and office space for the research associate, providing experimental animals (pigs) and slaughter facilities, conducting the research, preparing progress reports on project objectives, and preparing and submitting technical reports for publication.

All rights, title, and interest in any subject invention made solely by ARS employees are owned by ARS, solely by the Company are owned by the Company, and owned jointly between the Company and ARS if made jointly by ARS and the Company. The Company is granted an option to negotiate an exclusive license in each subject invention owned or co-owned by ARS for one or more field (s) of use encompassed by the agreement. Option terminates when the Company fails to (1) submit a complete application for an exclusive license within sixty days of being notified by ARS of an inventions availability for licensing or (2) submit a good faith written response to a written proposal of licensing terms within forty five days of such proposal.

The agreement, or parts thereof, is subject to termination at any time by mutual consent. Either party may unilaterally terminate the entire agreement at any time by giving the other party written notice not less than sixty calendar days prior to the desired termination date.

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## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

Cautionary Statement Pursuant to Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995:

Except for the historical information presented in this document, the matters discussed in this Form 10-QSB for the three months ending March 31, 2004, and specifically in the items entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations", or otherwise incorporated by reference into this document, contain "forward-looking statements" (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are identified by the use of forward-looking terminology such as "believes", "plans", "intend", "scheduled", "potential", "continue", "estimates", "hopes", "goal", "objective", "expects", "may", "will", "should" or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by the Company.

The reader is cautioned that no statements contained in this Form 10-QSB should be construed as a guarantee or assurance of future performance or results. These forward-looking statements involve risks and uncertainties, including those identified within this Form 10-QSB. The actual results that the Company achieves may differ materially from any forward-looking statements due to such risks and uncertainties. These forward-looking statements are based on current expectations, and the Company assumes no obligation to update this information. Readers are

urged to carefully review and consider the various disclosures made by the Company in this Form 10-QSB and in the Company's other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks and factors that may affect the Company's business.

## **Overview**

HepaLife Technologies, Inc. ([www.hepalife.com](http://www.hepalife.com)) is a development stage biotechnology company focused on the research, development and eventual commercialization of technologies and products to treat various forms of liver dysfunction and disease.

Through a Cooperative Research and Development Agreement (CRADA) with the USDA's Agricultural Research Service (ARS), the primary tool linking government and industry researchers, the Company is working towards optimizing the hepatic functionality of a patented cell line (PICM-19), whose hepatic characteristics have been demonstrated to have potential application in the production of a patented artificial liver device for use by human patients with liver failure.

The CRADA program, authorized under the Federal Technology Transfer Act of 1986, allows federal laboratories and businesses to form partnerships that help move new technologies to the marketplace and allows the collaborating company the first right to negotiate an exclusive license to inventions emerging under the agreement.

Through the CRADA, HepaLife gains access to proprietary technology, sophisticated scientific expertise and a fully equipped, established laboratory and research infrastructure that would otherwise be cost prohibitive for a development stage biotechnology company.

HepaLife's ongoing research and development work is being conducted under the auspices of and in collaboration with USDA scientists Dr. Neil C. Talbot (cell biologist) and Dr. Thomas J. Caperna (biochemist) at two USDA laboratories, the Growth Biology Laboratory and the Biotechnology and Germplasm Laboratory, both located at the Beltsville Agricultural Research Center in Beltsville, Maryland.

## **Liver Disease**

According to the American Liver Foundation approximately 25 million Americans are afflicted with liver disease. During 2001 alone, 27,035 people died in the United States as a consequence of cirrhosis and chronic liver disease (National Vital Statistics Report, September 18, 2003).

In purely economic terms, liver-related problems cost society over \$10 billion per year. In human terms, the costs cannot be calculated.

With over 500 documented functions, the liver is one of the most important and complex organs in the human body, primarily responsible for removing toxins and poisons from the bloodstream. Everything we eat, drink, and even smell, impacts the liver.

Each year, hundreds of thousands of individuals worldwide experience acute or chronic liver failure caused by hepatitis and other infections, degenerative diseases, trauma, drug overdoses and alcohol abuse. The last of these, alcohol abuse, is a major cause of liver disease in America today.

#### Alcohol Abuse

Of the nearly 14 million Americans (1 in every 20) that either abuse alcohol or are alcoholics (National Institute on Alcohol Abuse and Alcoholism), 10 to 20 percent will develop cirrhosis of the liver, one of the leading causes of death among young and middle-age adults in the US. Individuals with cirrhosis are particularly prone to developing fatal bacterial infections, kidney malfunctions, stomach ulcers, gallstones and cancer of the liver.

Chronic alcohol consumption may also increase the adverse side effects to the liver of medications used in the treatment of other conditions.

#### Drug Overdoses

Everyday pain relievers such as Bayer, Tylenol and Excedrin and other medications such as Neo-Citran and Sinutab, which contain acetaminophen, can also lead to serious liver problems. A study led by Dr. William Lee of the University of Texas, which was reported in the December 17, 2002, issue of Annals of Internal Medicine, concluded that acetaminophen overdose and drug reactions have replaced viral hepatitis as the most frequent apparent cause of acute liver failure.

According to the National Hospital Ambulatory Medical Care Survey (April 22, 2002), there were 108 million patient visits to emergency rooms during 2000, with medications being used in 74% of all these visits. An average of 1.6 drugs were used per emergency department visit, with pain relief medications containing acetaminophen being the most frequently administered class of drug.

One of the functions of the liver is the detoxification of drugs and poisons. When experienced in large amounts, often the case in hospital emergency wards, or in combination with alcohol, drugs or poisons, the toxic overload can destroy the liver quickly. Each year, tens of thousands of individuals die due to acute liver failure as a result of drug overloads in emergency rooms worldwide.

### Hepatitis

According to the Centers for Disease Control, between 15-25% (upwards of 312,500 Americans) of the estimated 1.25 million chronically infected hepatitis B sufferers will die from chronic liver disease. Globally, an estimated 300 million people are infected with hepatitis B, causing approximately 1,000,000 deaths per year.

Various studies, when combined together, suggest that over 200 million people around the world are infected with hepatitis C. Statistically, as many people are infected with hepatitis C as are with HIV, the virus that causes AIDS. Of the estimated 4.5 million Americans infected with hepatitis C, for which there is no cure, an estimated 70-80% will develop chronic liver disease and 20% will die. The annual health care costs for the affected U.S. population with chronic hepatitis C has been estimated to be as high as \$9 billion, compared to annual cost of \$360 million for hepatitis B sufferers.

In addition to alcohol abuse, drug overdoses and hepatitis, other causes of liver disease include primary biliary cirrhosis, hemochromatosis, Wilson's disease, alpha1-antitrypsin deficiency, glycogen storage disease, autoimmune hepatitis, cardiac cirrhosis and schistosomiasis. In total, according to the American Liver Foundation, approximately 25 million Americans are afflicted with liver disease.

### Liver Transplants

For people with severe liver failure, orthotopic liver transplantation is the only effective treatment therapy, now an estimated \$1.5 billion business. At present, there are upwards of 17,000 adults and children medically approved and waiting for liver transplants in the U.S., which, at approximately \$300,000 per transplant, would increase the potential size of the liver transplant market to over \$5 billion if enough donor organs were available.

Unfortunately, there are just over 5,000 livers available for transplant annually. Due to a severe shortage of organ donors, the waiting time for potential liver recipients could be as long as two to three years, with 20-30% of these patients not surviving the wait period.



For those who receive liver transplants, some 31% will die within 5 years, while the rest will endure a life time of immunosuppressive drugs, rendering them susceptible to life threatening infections such as kidney failure and increased risk of cancer, and follow up costs of \$25,000 per year to the health care system.

Sadly, patients suffering from advanced liver failure who are either not whole organ transplant candidates or who cannot find an available organ in a timely fashion have limited prospects for survival. As a result, the need for an artificial liver device able to remove toxins and improve immediate and long-term survival results for patients suffering from liver disease is more critical today than ever before.

#### An Artificial Liver Device Would Provide Temporary Support

To help liver failure patients survive long enough to receive a liver transplant or recover without a transplant as a result of the well known regenerative powers of the liver, a number of artificial liver devices are currently being developed and tested using living pig or human liver cells and various filtering or dialysis mechanisms.

Since the liver is the only organ in the human body that can regenerate itself, artificial liver devices are intended to temporarily perform the function of a human liver, such as removing toxins from the body, thus giving the patient's own liver valuable time to recover and regenerate.

Unfortunately, artificial liver technologies have not lived up to their initial promise, with problems relating to the inability to grow liver cells quickly and safely enough and with inconsistent results from filtering devices. Culturing and maintaining such cells has proven difficult; once removed from the body, they soon lose their normal function.

To date, the cellular components of artificial liver devices that are being tested are based on freshly isolated porcine hepatocytes, human transformed tumor cells, or poorly defined stem-like cells prepared from fresh human adult liver tissue.

It is widely recognized that the greatest hindrance to the development of a completely functional artificial liver rescue device is the lack of an appropriately defined cell line that will provide the functions of an intact liver. One such stem-like cell line is the patented PICM-19 cell line, which is being studied through a collaborative research and development agreement by HepaLife Technologies for potential use in the production of artificial liver device for human patients with liver failure.

Derived from porcine epiblast (embryonic) tissue, the PICM-19 cell line is not tumor-causing, a feature critical to nutrient metabolism research, and even after years in continuous culture, the cell line has retained its desired

properties. For these and other reasons, HepaLife's research is focused on developing experimental culture conditions for the PICM-19 cell line or other pig epiblast derived liver cell lines so as to optimize their hepatocyte functions for use in the production of an artificial liver device.

Our Research Objectives

The overall objective of our collaborative research work is to optimize the culture conditions for the PICM-19 liver stem cell line so that the cells grow faster, reach higher densities, and have good function of key liver metabolic and detoxification enzyme systems. Concurrent with these cell biology efforts and those listed below, bioengineering investigations on the cell culture hardware of an artificial liver device are ongoing.

Other specific research objectives are:

- 
- Develop cell culture system allowing the growth and differentiation of PICM-19 cells without STO feeder cell support;
- 
- develop serum-free, defined or semi-defined medium cell culture system for growth and differentiation of PICM-19 cells;
- 
- develop spheroid cultures of PICM-19 cells and test of rotating cell culture system (RCCS) or production and maintenance of spheroids;
- 
- assay PICM-19 monolayer cultures and spheroid cultures for liver specific functions; inducible P450 activity and content, -glutamyltranspeptidase activity, urea production, and ammonia clearance;
- 
- assay PICM-19 liver specific protein synthesis and secretion by electrophoretic and immunochemical techniques;
- 
- assay liver specific markers in PICM-19 by immunocytochemistry;
-

Document PICM-19 hepatocyte morphology by light and electron microscopy.

Ideally, further characterization and improvements required in the culture technology will result in the cell line not requiring feeder cell support and growth in a completely serum-free defined medium. These advancements would facilitate the objective of adapting and applying the optimized PICM-19 cell line technology to the development of an artificial liver device.

HepaLife's ongoing research and development work is being conducted at two USDA laboratories, the Growth Biology Laboratory and the Biotechnology and Germplasm Laboratory, both located at the Beltsville Agricultural Research Center in Beltsville, Maryland.

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### **Critical Accounting Policies**

Our discussion and analysis or plan of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to income taxes and contingencies. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies reflect its more significant estimates and assumptions used in the preparation of its financial statements:

**Income Taxes** - We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have considered future market growth, forecasted earnings, future taxable income, and prudent and feasible tax planning strategies in determining the need for a valuation allowance. We currently have recorded a full valuation allowance against net deferred tax assets as we currently believe it is more likely than not that the deferred tax assets will not be realized

Contingencies - We may be subject to certain asserted and unasserted claims encountered in the normal course of business. It is our belief that the resolution of these matters will not have a material adverse effect on our financial position or results of operations, however, we cannot provide assurance that damages that result in a material adverse effect on our financial position or results of operations will not be imposed in these matters. We account for contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

### **Results of operations**

General and administrative expenses: During the three months ended March 31, 2004, and March 31, 2003, the Company incurred \$76,016 and \$13,455, respectively, in general and administrative expenses, an increase of 465%, attributable to an increase in salary, marketing and operating expenses.

Interest income: Interest income was \$552 for the three month period ended March 31, 2004 versus \$70 for the same period in 2003. The increase in interest income is a direct result of changes in interest rates and an increase in cash balance. Interest earned in the future will be dependent on Company funding cycles and prevailing interest rates.

Provision for income taxes: As of ended March 31, 2004, the Company's accumulated deficit was \$2,408,323 and as a result, there has been no provision for income taxes to date.

Net income (loss): For the three months ended March 31, 2004, and for the same period in 2003, the Company recorded a net loss of \$96,164 and \$13,385 respectively.

### **Liquidity and Capital Resources**

As at March 31, 2004, the Company had a cash balance of \$381,461. The Company has financed its operations primarily through cash on hand during the three month period ending March 31, 2004.

Net cash flows used in by operating activities was \$97,390 for the three month period ending March 31, 2004, compared to net cash flows used of \$6,497 for the same period in 2003, primarily due to increased operating costs. The Company believes it has sufficient cash to satisfy its cash requirements for the next twelve months.

**Plan of Operations**

The Company's current business includes a Cooperative Research and Development Agreement entered into with the United States Department of Agriculture's Agricultural Research Service to fund the research and development involving optimizing the function of a patented cell line and applying this technology to the development of extra corporeal liver assist device.

The Company anticipates that its major shareholder will contribute sufficient funds to satisfy the cash needs of the Company through calendar year ending December 31, 2004, however, if necessary additional funds maybe provided by loans from shareholders or debt/equity financings.

Due to the "start up" nature of the Company's businesses, the Company expects to incur losses as it expands. The Company expects to raise additional funds through private or public equity investment in order to expand the range and scope of its business operations. The Company will seek access to private or public equity but there is no assurance that such additional funds will be available for the Company to finance its operations on acceptable terms, if at all. See "Risk Factors" for additional details.

On November 1st, 2002, the Company entered into a Cooperative Research and Development Agreement (the agreement) with the United States Department of Agriculture's (USDA) Agricultural Research Service (ARS), and committed a total payment of \$292,727 to ARS over two year period, as listed below:

- (1) \$91,500 within 30 days of signing the Agreement; (paid in 2002)
- (2) \$20,700 on or before 8/19/03; (paid 2003)
- (3) \$20,700 on or before 11/19/03; (paid 2003)
- (4) \$20,700 on or before 2/19/04; (paid 2004)
- (5) \$91,500 on or before 5/19/04;
- (6) \$15,875 on or before 8/19/04;
- (7) \$15,876 on or before 11/19/04; and
- (8) \$15,876 on or before 2/19/05

The agreement is for the purpose of funding salaries, equipment, travel and other indirect costs of a post-doctoral research associate. The terms of the agreement require the interaction of the Company with ARS personnel on the

technical details involved with pig liver cell culture development, providing the necessary funds for the purpose above, preparing and filing any patent applications, and reviewing reports and implementing procedures for the development of an artificial liver device utilizing the pig liver cell line. ARS's responsibilities include hiring the post-doctoral research associate for a two-year period, providing laboratory and office space for the research associate, providing experimental animals (pigs) and slaughter facilities, conducting the research, preparing progress reports on project objectives, and preparing and submitting technical reports for publication.

All rights, title, and interest in any subject invention made solely by ARS employees are owned by ARS, solely by the Company are owned by the Company, and owned jointly between the Company and ARS if made jointly by ARS and the Company. The Company is granted an option to negotiate an exclusive license in each subject invention owned or co-owned by ARS for one or more field (s) of use encompassed by the agreement. Option terminates when the Company fails to (1) submit a complete application for an exclusive license within sixty days of being notified by ARS of an inventions' availability for licensing or (2) submit a good faith written response to a written proposal of licensing terms within forty five days of such proposal.

The agreement, or parts thereof, is subject to termination at any time by mutual consent. Either party may unilaterally terminate the entire agreement at any time by giving the other party written notice not less than sixty calendar days prior to the desired termination date.

### **Related Party Transactions**

**Management Fees:** During the three months ended March 31, 2004 and 2003, the Company charged \$0 and \$9,000, respectively, to operations for management and consulting fees incurred for services rendered by Mr. Harmel S. Rayat, a Director, Secretary/Treasurer and majority shareholder of the Company. As of March 31, 2004, the Company owed \$27,000 for outstanding management fees, which is included in accounts payable and accrued liabilities. There is no management or consulting agreement in effect nor is there an agreement in place to convert debt to equity, which is done at the discretion of Mr. Rayat and upon approval by the board of directors.

**Notes Payable and Accrued Interest:** Notes payable totally \$725,000 as at March 31, 2004, represents unsecured loans of \$300,000 (due on May 29, 2004 and bearing an interest rate of 7.25%), \$350,000 (due on August 28, 2004 and bearing an interest rate of 7.00%) and \$75,000 (due on November 19, 2004 and bearing an interest rate of 7.00%) due to Mr. Harmel S. Rayat, a Director, Secretary/Treasurer and majority shareholder of the Company. Accrued and unpaid interest on these notes during the three month period ended March 31, 2004, amounted to \$12,875.

**Properties:** The Company's principal office is located at 1628 West First Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. These premises are owned by a private corporation controlled by a director and majority shareholder of the Company. At present, HepaLife pays no rent and we believe that the existing facilities are adequate to meet our requirements for the near term. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

### **Recent Accounting Pronouncements**

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46 "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51" (FIN 46). FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. Management does not anticipate that FIN 46 will have any effect on the on the Company.

In April 2003, the FASB issued SFAS No. 149, "Accounting for Amendment of Statement 133 on Derivative Instruments and Hedging Activities," which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities. This Statement is generally effective for 45 contracts entered into or modified after June 30, 2003, and all provisions should be applied prospectively. This statement does not affect the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity," which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. This statement does not affect the Company.

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### **Risk Factors**

*We have sought to identify what we believe to be the most significant risks to our business. However, we cannot predict whether, or to what extent, any of such risks may be realized nor can we guarantee that we have identified all possible risks that might arise. Investors should carefully consider all of such risk factors before making an investment decision with respect to our Common Stock. We provide the following cautionary discussion of risks, uncertainties and possible inaccurate assumptions relevant to our business. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed here could adversely affect us.*

Our business is at an early stage of development.

Our business is at an early stage of development. Our ability to produce a product that progresses to and through clinical trials is subject to numerous uncertainties, including but not limited to, the continued success of our research and development efforts, our ability to finance the Company's ongoing research and development operations, our ability to attract and retain appropriate personnel and attaining appropriate regulatory approvals. Our efforts may not result in a product that can be marketed or manufactured in commercial quantities at an acceptable cost. Because of the significant scientific, regulatory and commercial milestones that must be reached in order to be successful, we may abandon any product, even after significant resources have been expended.

We are vulnerable to volatile market conditions.

The market prices for securities of developmental stage biotechnology companies, including ours, are highly volatile and, from time to time, experience significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, future announcements, such as the results of our research, media coverage, testing and clinical trials, the status of our relationships with third-party collaborators, technological innovations or new products, services or drugs, legislation and governmental regulation, developments in patent or other proprietary rights, litigation or public concern as to the safety of products developed by us or others and general market conditions, concerning us, our competitors or other companies, may have a significant effect on the market price of our common stock.

We face intense competition.

We face intense competition from a wide range of pharmaceutical, biopharmaceutical, biotechnology and medical device companies, as well as academic and research institutions and government agencies. Our competitors include organizations that are pursuing the same or similar technologies as us and organizations that are pursuing products that are competitive with our potential product. To the extent that these technologies or products address the problems associated with liver disease on which we have focused, they may represent significant competition.



Many of the organizations competing against us have financial and other resources substantially greater than our own. In addition, many of our competitors have significantly greater experience in research and development, obtaining FDA and other regulatory approvals, and commercializing and selling products for use in health care. Accordingly, our competitors may succeed more rapidly than we will in completing clinical trials, obtaining various regulatory approvals or achieving market penetration for products. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than our products and may be more effective and less costly. If we commence significant commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no experience.

We will continue to incur operating losses.

Our business operations began in 1997 and we have a limited operating history. We may encounter delays, uncertainties and complications typically encountered by development stage biotechnology businesses. We have generated no revenues, are not profitable and have incurred an accumulated deficit of \$2,408,323 since our inception. The Company's current ability to generate revenues and to achieve profitability and positive cash flow will depend on the successful commercialization of our products currently under development. However, even if we eventually generate revenues from sales of our products currently under development, we expect to incur significant operating losses over the next several years. Our ability to become profitable will depend, among other things, on our (1) successful research outcomes and eventual development of our proposed products, (2) obtaining of regulatory approvals of our proposed products on a timely basis and (3) success in joint venture partnerships, manufacturing, distributing and marketing our proposed products.

We may never receive material revenues from product sales or if we do generate revenues, such revenues may not be sufficient to continue or expand our research or development activities and otherwise sustain our operations.

We may not obtain additional financing.

While we anticipate that our existing funds will be sufficient to fund our operating and research requirements as currently planned into the second quarter of 2005, we cannot guarantee that this will be sufficient. We expect to use, rather than generate, funds from operations for the foreseeable future, and as a result, we will need significant funding to pursue our research, development and commercialization plans. The actual amount of funds we will require will be determined by a number of factors, many of which are beyond our control, including continued scientific progress in our research and development programs, magnitude and scope of our research and development programs, costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and the potential development of new technologies and products.

If we cannot raise more funds, we could be required to scale back or abandon our research and product development activities, reduce our workforce and license to others products or technologies we would otherwise seek to commercialize ourselves. Our products under development will require significant time-consuming and costly

research and development, clinical testing, regulatory approval and significant additional investment prior to their commercialization. There can be no assurance that (1) the research and development activities we conduct will be successful, (2) current or future products or technologies under development will prove to be safe and effective, (3) any of the clinical development work will be completed, or (4) the anticipated products or technologies will be commercially viable or successfully marketed. Commercial sales of our products cannot begin until we receive final FDA approval.

We will seek additional funding through collaborative arrangements, by borrowing money or by selling additional equity securities. Any sales of additional equity securities are likely to result in further dilution to our then existing stockholders. Further, if we issue additional equity securities, the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock. We may also borrow money from conventional lenders, possibly at high interest rates and on other terms that are unfavorable to us, which will increase the risk of your holdings. Despite our efforts, additional funding may not be available to us at all or only on terms that are unacceptable to us. We also could be required to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products which we would otherwise pursue on our own

We may not be able to protect our intellectual property.

The Company relies on a combination of copyright law, trade secret protection, confidentiality agreements and other contractual arrangements with employees, vendors and others to protect its rights to intellectual property. These measures, however, may be inadequate to deter misappropriation of proprietary information. Failure to adequately protect its intellectual property could harm the Company, devalue its proprietary content and affect the Company's ability to compete effectively.

We may lose important research and invention licenses.

We are a party to a Cooperative Research and Development Agreement with the United States Department of Agriculture's Agricultural Research Service which grants the Company an option to negotiate an exclusive license to any invention or other intellectual property conceived or reduced to practice under the Agreement which is patentable or otherwise protectable under Title 35 of the United States Code or under the patent laws of a foreign country. There can be no assurance that such a license will be granted to us or that we can obtain a license on terms favorable to us. If we do not obtain an exclusive license, our ability to generate revenue would be adversely affected.

We expect to enter into additional research agreements and licenses in the future that relate to important technologies that may be necessary for the development and commercialization of related and unrelated products. These agreements and licenses may impose various commercialization, indemnification, royalty, insurance and other obligations on us, which, if we fail to comply may result in the termination of these agreements and licenses or make the agreements and licenses non-exclusive, which could affect our ability to exploit important technologies that are

required for successful development of our products.

We may not be able to obtain patent protection and may infringe upon the property rights of others.

Our success depends in significant part on our ability to obtain important research and invention licenses, obtain patents, protect trade secrets, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights.

If we do obtain patents, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until patents issue, third parties may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We may not hold proprietary rights to all of the patents related to our proposed products or services. These patents may be owned or controlled by third parties. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to market our proposed products or services. If licenses are not available on acceptable terms, we or our collaborative partners will not be able to market these products or services.

You may lack an effective vote on corporate matters due to control by management.

You may lack an effective vote on corporate matters and management may be able to act contrary to your objectives. As of April 30, 2004, our officers and board members own 45,213,056 of the 64,390,832 outstanding common shares, not including stock options and warrants. If management votes together, it could influence the outcome of corporate actions requiring shareholder approval, including the election of directors, mergers and asset sales. As a result, new stockholders may lack an effective vote with respect to the election of directors and other corporate matters. Therefore, it is possible that management may take actions with respect to its ownership interest, which may not be consistent with your objectives or desires.

We may experience significant fluctuations in quarterly results.

Significant variations in our quarterly operating results may adversely affect the market price of our common stock. Our operating results have varied on a quarterly basis during our limited operating history, and we expect to experience significant fluctuations in future quarterly operating results. These fluctuations have been and may in the future be caused by numerous factors, many of which are outside of our control. We believe that period-to-period

comparisons of our results of operations will not necessarily be meaningful and that you should not rely upon them as an indication of future performance. Also, it is likely that our operating results could be below the expectations of public market analysts and investors. This could adversely affect the market price of our common stock.

We depend on our key executive officers and technical personnel.

The success of our business plan depends on attracting qualified technical, scientific and other knowledgeable personnel, and failure to retain the necessary personnel could adversely affect our business. Competition for qualified personnel is intense, and we may need to pay premium wages to attract and retain personnel. Attracting and retaining qualified personnel is critical to our business. Inability to attract and retain the qualified personnel necessary would limit our ability to implement our business plan successfully.

We may not have a majority of independent directors.

We cannot guarantee our Board of Directors will have a majority of independent directors in the future. In the absence of a majority of independent directors, our executive officers, who are also principal stockholders and directors, could establish policies and enter into transactions without independent review and approval thereof. This could present the potential for a conflict of interest between the Company and its stockholders generally and the controlling officers, stockholders or directors.

Our Articles and By-Laws indemnify our officers and directors.

Our officers and directors are required to exercise good faith and high integrity in our management affairs. Our Articles of Incorporation and By Laws provide, however, that our officers and directors shall have no liability to our shareholders for losses sustained or liabilities incurred which arise from any transaction in their respective managerial capacities unless they violated their duty of loyalty, did not act in good faith, engaged in intentional misconduct or knowingly violated the law, approved an improper dividend or stock repurchase, or derived an improper benefit from the transaction. Our Articles and By-Laws also provide for the indemnification by us of the officers and directors against any losses or liabilities they may incur as a result of the manner in which they operate our business or conduct the internal affairs, provided that in connection with these activities they act in good faith and in a manner they reasonably believe to be in, or not opposed to, the best interests of the Company, and their conduct does not constitute gross negligence, misconduct or breach of fiduciary obligations.

Large sales of common stock could adversely affect our common stock and our ability to raise capital.

Future sales of our common stock by existing stockholders pursuant to Rule 144 under the Securities Act, or following the exercise of outstanding options and warrants, could adversely affect the market price of our common stock. Substantially all of the outstanding shares of our common stock are freely tradable, without restriction or registration under the Securities Act, other than the sales volume restrictions of Rule 144 applicable to shares held beneficially by persons who may be deemed to be affiliates. Our directors and executive officers and their family members are not under lockup letters or other forms of restriction on the sale of their common stock. The issuance of any or all of these additional shares upon exercise of options or warrants or conversion of preferred stock will dilute the voting power of our current stockholders on corporate matters and, as a result, may cause the market price of our common stock to decrease. Further, sales of a large number of shares of common stock in the public market could adversely affect the market price of the common stock and could materially impair our future ability to generate funds through sales of common stock or other equity securities.

We are considered a penny stock.

The Company's stock differs from many stocks, in that it is a "penny stock." The Securities and Exchange Commission has adopted a number of rules to regulate "penny stocks." These rules include, but are not limited to, Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6 and 15g-7 under the Securities and Exchange Act of 1934, as amended.

Because our securities probably constitute "penny stock" within the meaning of the rules, the rules would apply to us and our securities. The rules may further affect the ability of owners of our stock to sell their securities in any market that may develop for them. There may be a limited market for penny stocks, due to the regulatory burdens on broker-dealers. The market among dealers may not be active. Investors in penny stock often are unable to sell stock back to the dealer that sold them the stock. The mark-ups or commissions charged by the broker-dealers may be greater than any profit a seller may make. Because of large dealer spreads, investors may be unable to sell the stock immediately back to the dealer at the same price the dealer sold the stock to the investor. In some cases, the stock may fall quickly in value. Investors may be unable to reap any profit from any sale of the stock, if they can sell it at all.

Stockholders should be aware that, according to the Securities and Exchange Commission Release No. 34- 29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. These patterns include:

- Control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- Manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "Boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;

-Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

-The wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Furthermore, the "penny stock" designation may adversely affect the development of any public market for the Company's shares of common stock or, if such a market develops, its continuation. Broker-dealers are required to personally determine whether an investment in "penny stock" is suitable for customers.

Penny stocks are securities (i) with a price of less than five dollars per share; (ii) that are not traded on a "recognized" national exchange; (iii) whose prices are not quoted on the NASDAQ automated quotation system (NASDAQ-listed stocks must still meet requirement (i) above); or (iv) of an issuer with net tangible assets less than \$2,000,000 (if the issuer has been in continuous operation for at least three years) or \$5,000,000 (if in continuous operation for less than three years), or with average annual revenues of less than \$6,000,000 for the last three years.

Section 15(g) of the Exchange Act, and Rule 15g-2 of the Commission require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. Potential investors in the Company's common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be "penny stock."

Rule 15g-9 of the Commission requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for the Company's stockholders to resell their shares to third parties or to otherwise dispose of them.

We will be subject to approval by regulatory authorities and are subject to government regulation.

Some of our products will be subject to regulation in the United States by the Food and Drug Administration and by comparable regulatory authorities in foreign jurisdictions. The Company's artificial liver device will be classified as a "biologic" regulated under the Public Health Service Act and the Food, Drug and Cosmetic Act. Development of a therapeutic product for human use is a multi-step process. First, animal and in vitro testing must establish the potential safety and efficacy of the experimental product for a given disease. Once the product is found to be reasonably safe and potentially efficacious in animals, suggesting that human testing would be appropriate, an Investigational New Drug ("IND") application is submitted to the FDA. FDA approval, which may in some circumstances involve substantial delays, is necessary before commencing clinical investigations.

Clinical investigations typically involve three phases. Phase I is conducted to evaluate the safety of the experimental product in humans, and if possible to obtain early evidence of effectiveness. Phase I studies also evaluate various routes, dosages and schedules of product administration. The demonstration of therapeutic benefit is not required in order to complete Phase I successfully. If acceptable product safety is demonstrated, the Phase II studies are initiated, which are designed to evaluate the effectiveness of the product in the treatment of a given disease and typically, are well controlled and closely monitored studies in a relatively small number of patients. Phase II studies determine the optimal routes and schedules of administration.

If Phase II trials are successfully completed, Phase III studies will commence. Phase III studies are expanded controlled and uncontrolled trials which are intended to gather additional information about safety and efficacy in order to evaluate the overall risk and/ or benefit relationship of the experimental product and provide an adequate basis for physician labeling. These studies also may compare the safety and efficacy of the experimental device with currently available products. While it is not possible to estimate the amount of time or money that will be required to complete Phase I, II and III studies, this process often lasts several years.

Following the successful completion of these clinical investigations, the preclinical and clinical evidence that has been accumulated is submitted to the FDA as part of a product license application ("PLA"). Approval of the PLA or IND is necessary before a company may market the product. The approval process can be very lengthy and depends upon the time it takes to review the submitted data and the FDA's comments on the application, and the time required to provide satisfactory answers or additional clinical data when requested.

We must be compliant with environmental matters and regulations.

We are subject to regulation under state and federal law, including requirements regarding occupational safety, laboratory practices, the use, handling and disposition of radioactive materials, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, federal and foreign regulation, including future regulation of the biotechnology field. The Company believes it conducts its business in compliance with all environmental laws presently applicable to its facilities. To date, there have been no expenses incurred by the Company related to environmental issues.

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**ITEM 3. Controls and Procedures**

a. Evaluation of Disclosure Controls and Procedures:

Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports filed under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based upon and as of the date of that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports the Company files and submits under the Exchange Act is recorded, processed, summarized and reported as and when required.

b. Changes in Internal Control over Financial Reporting:

There were no changes in the Company's internal control over financial reporting identified in connection with the Company evaluation of these controls as of the end of the period covered by this report that could have significantly affected those controls subsequent to the date of the evaluation referred to in the previous paragraph, including any correction action with regard to significant deficiencies and material weakness.

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**PART II Other Information**



Item 1. Legal Proceedings

None

Item 2. Changes in Securities

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 and Reports on Form 8-K

(a) Exhibits

31.1

Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)

31.2

Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)

32.1

Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2

Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

January 8, 2004: HepaLife Technologies, Inc. issued a news release announcing results of First Phase Research with an improved cell line developed yielding 2-3 times cell density; positive research results obtained from key enzyme systems; and the beginning of bioreactor device development and testing.

January 16, 2004: HepaLife Technologies, Inc. announced the dismissal of Clancy and Co., P.L.L.C. and the appointment of Moore Stephens Ellis Foster Ltd., LLP to act as the Company's independent auditor.

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**SIGNATURES**

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Pursuant to the requirements of Sections 13 or 15 (d) of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 13th day of May, 2004.

HepaLife Technologies, Inc.

/s/ Arian Soheili

Arian Soheili

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in capacities and on the dates indicated.

Signature

Title

Date

/s/ Arian Soheili

Director , President,

May 13, 2004

Arian Soheili

Chief Executive Officer

/s/ Jasvir Kheleh

Director

May 13, 2004

Jasvir Kheleh

/s/ Harmel Rayat

Director, Secretary/Treasurer,

May 13, 2004

Harmel Rayat

Principal Financial Officer

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Arian Soheili, certify that:

- (1) I have reviewed this quarterly report on Form 10-QSB of HepaLife Technologies, Inc. (the registrant );
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The small business issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our

conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2004

By: /s/ Arian Soheili  
Arian Soheili  
President and Chief Executive Officer

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**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Harmel Rayat certify that:

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

the small business issuer's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2004

By: /s/ Harmel Rayat  
Harmel Rayat  
Principal Financial Officer

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**Exhibit 32.1**

**Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350  
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of HepaLife Technologies, Inc. (the Company) on the Form 10-QSB for the period ending March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Arian Soheili, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

- (i) the Report filed by the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (ii)



The information contained in that Report fairly presents, in all material respects, the financial condition and results of operations of the Company on the dates and for the periods presented therein.

**HEPALIFE TECHNOLOGIES, INC.**

Date: May 13, 2004

By:

/s/ Arian Soheili

Arian Soheili

President and Chief Executive Officer

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**Exhibit 32.2**

**Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350**

**as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of HepaLife Technologies, Inc. (the Company ) on the Form 10-QSB for the period ending March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the Report ), I, Harmel Rayat, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

(i)

the Report filed by the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(ii)

The information contained in that Report fairly presents, in all material respects, the financial condition and results of operations of the Company on the dates and for the periods presented therein.

**HEPALIFE TECHNOLOGIES, INC.**

Date: May 13, 2004

By:

/s/ Harmel Rayat

Harmel Rayat

Principal Financial Officer

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.