HEPALIFE TECHNOLOGIES INC Form DEF 14A August 15, 2005

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

#### **SCHEDULE 14A**

Proxy Statement Pursuant to Section 14(a)

of the Securities Exchange Act of 1934

Filed by the Registrant [X]

Filed by a Party other than the Registrant [ ]

Check the appropriate box:

[] Preliminary Proxy Statement

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

- [X] Definitive Proxy Statement
- [ ] Definitive Additional Materials
- [] Soliciting Material Pursuant to §240.14a-12

#### **HEPALIFE TECHNOLOGIES, INC.**

(Name of Registrant As Specified In Its Charter)

Payment of Filing Fee (Check the appropriate box):

#### [X] No fee required

- [] Fee computed on table below per Exchange Act Rules 14a-6(i)(4) and 0-11.
- 1) Title of each class of securities to which transaction applies:

2) Aggregate number of securities to which transaction applies:

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

4) Proposed maximum aggregate value of transaction:

5) Total fee paid:\_\_\_\_\_

[ ] Fee paid previously with preliminary materials.

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

1) Amount Previously Paid:\_\_\_\_\_

2) Form, Schedule or Registration Statement No.:\_\_\_\_\_

3) Filing Party:\_\_\_\_\_

4) Date Filed:\_\_\_\_

#### **HEPALIFE TECHNOLOGIES, INC.**

Suite 216 1628 West 1st Ave.

Vancouver, B.C. V6J 1G1

Telephone: 800-518-4879

July 26, 2005

Dear Stockholders:

You are cordially invited to attend the 2005 Annual Meeting of Stockholders of HepaLife Technologies, Inc. The meeting will be held at 1:00 p.m., local time, on September 7, 2005, at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1. Enclosed are the official notice of this meeting, a proxy statement, a form of proxy and the 2004 Annual Report on Form 10-KSB for the year ended December 31, 2004.

At this meeting you will be asked to elect directors to serve until the next annual meeting, ratify the selection of the Company's independent auditors for 2005 and to transact any other business as may properly come up before the meeting.

Please note that attendance at the Annual Meeting will be limited to stockholders of record at the close of business on June 30, 2005, and to guests of the Company. If your shares are registered in your name and you plan to attend the Annual Meeting, please bring the enclosed ballot with you to the meeting. If your shares are held by a broker, bank or other nominee and you plan to attend the meeting, please contact the person responsible for your account regarding your intention to attend the meeting so they will know how you intend to vote your shares at that time. Stockholders who do not expect to attend the Annual Meeting in person may submit their ballot to the Management of the Company at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1.

## BY ORDER OF THE BOARD OF DIRECTORS

/s/ Harmel S. Rayat

Harmel S. Rayat

Secretary, Treasurer, Director

## NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

## OF HEPALIFE TECHNOLOGIES, INC. TO BE HELD SEPTEMBER 7, 2005

To the Stockholders of HepaLife Technologies, Inc.:

NOTICE IS HEREBY GIVEN that the 2005 Annual Meeting of Stockholders (the "Annual Meeting") of HepaLife Technologies, Inc., a Florida corporation (the "Company"), will be held at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., on the 7th day of September, 2005, at 1:00 p.m. (local time) for the following purposes:

To elect 3 directors to the Board of Directors to serve until the next Annual Meeting of stockholders or until their respective successors are duly elected and have qualified;

2.

To ratify the appointment of Ernst and Young, LLP as the Company's independent auditor for the fiscal year ending December 31, 2005;

3.

To transact any and all other business that may properly come before the Annual Meeting or any adjournment(s) thereof.

Pursuant to the Company's Bylaws (the "Bylaws"), the record date (the "Record Date") for the determination of stockholders entitled to notice of and to vote at such meeting or any adjournment(s) thereof shall be the close of business on June 30, 2005. Only holders of record of the Company's Common Stock at the close of business on the Record Date are entitled to notice of and to vote at the Annual Meeting. Shares can be voted at the Annual Meeting only if the holder is present or represented by proxy. The stock transfer books will not be closed. A copy of the Company's 2004 Annual Report to Stockholders, in the form of the 10-KSB filed with the Securities and Exchange Commission, which includes audited financial statements, has been included in this mailing to the Company's stockholders. A list of stockholders entitled to vote at the Annual Meeting.

You are cordially invited to attend the Annual Meeting; whether or not you expect to attend the meeting in person, however, you are urged to mark, sign, date, and mail or telefax the enclosed form of proxy promptly so that your shares of stock may be represented and voted in accordance with your wishes and in order that the presence of a quorum may be assured at the meeting. Your proxy will be returned to you if you should be present at the Annual Meeting and should request its return in the manner provided for revocation of proxies on the initial page of the enclosed proxy statement.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ Harmel S. Rayat

Harmel S. Rayat

Secretary, Treasurer, Director

Vancouver, BC,

July 26, 2005

#### **HEPALIFE TECHNOLOGIES, INC.**

## Suite 216 1628 West 1st Avenue

#### Vancouver, BC V6J 1G1

## PROXY STATEMENT FOR ANNUAL MEETING OF STOCKHOLDERS

## **TO BE HELD SEPTEMBER 7, 2005**

## SOLICITATION AND REVOCABILITY OF PROXIES

The accompanying proxy is solicited by the Board of Directors on behalf of HepaLife Technologies, Inc., a Florida corporation (the "Company"), to be voted at the 2005 Annual Meeting of Stockholders of the Company (the "Annual Meeting") to be held on September 7, 2005, at the time and place and for the purposes set forth in the accompanying Notice of Annual Stockholders (the "Notice") and at any adjournment(s) thereof. When proxies in the accompanying form are properly executed and received, the shares represented thereby will be voted at the Annual Meeting in accordance with the directions noted thereon; if no direction is indicated, such shares will be voted FOR the election of the nominees listed thereon, FOR the ratification of the independent auditor, and in their discretion with respect to any other matters that may properly come before the stockholders at the Annual Meeting.

The executive offices of the Company are located at, and the mailing address of the Company is, Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1.

Management does not anticipate that any matters will be presented at the Annual Meeting other than matters set forth in the Notice.

This proxy statement (the "Proxy Statement") and accompanying proxy are being mailed on or about August 10, 2005. The Company's Annual Report on Form 10-KSB (the "2004 Annual Report"), which serves as the Annual Report to Stockholders, covering the Company's fiscal year ended December 31, 2004, is attached.

Any stockholder of the Company giving a proxy has the right to revoke their proxy at any time prior to the voting thereof by voting in person at the Annual Meeting, by delivering a duly executed proxy bearing a later date or by giving written notice of revocation to the Company addressed to Harmel S. Rayat, Secretary/Treasurer, Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1; no such written notice shall be effective, however, until such notice of revocation has been received by the Company at or prior to the Annual Meeting.

In addition to the solicitation of proxies by use of the mail, officers and regular employees of the Company may solicit the return of proxies, either by mail, telephone, telefax, telegraph or through personal contact. Such officers and employees will not be additionally compensated but will be reimbursed for out- of-pocket expenses. Brokerage houses and other custodians, nominees, and fiduciaries will, in connection with shares of the Company's common stock, \$0.001 par value per share (the "Common Stock"), registered in their names, be requested to forward solicitation material to the beneficial owners of such shares of Common Stock.

The cost of preparing, printing, assembling, and mailing the 2004 Annual Report, the Notice, this Proxy Statement, and the enclosed form of proxy, as well as the cost of forwarding solicitation materials to the beneficial owners of shares of Common Stock and other costs of solicitation, are to be borne by the Company.

## QUORUM AND VOTING

The record date for the determination of stockholders entitled to notice of and to vote at the Annual Meeting was the close of business on June 30, 2005 (the "Record Date"). On the Record Date, there were 69,332,832 shares of Common Stock issued and outstanding.

Each share of Common Stock is entitled to one vote on all matters to be acted upon at the Annual Meeting, and neither the Company's Certificate of Incorporation (the "Certificate of Incorporation") nor its Bylaws allow for cumulative voting rights. The presence, in person or by proxy, of the holders of a majority of the issued and outstanding Common Stock entitled to vote at the meeting is necessary to constitute a quorum to transact business. If a quorum is not present or represented at the Annual Meeting, the stockholders entitled to vote thereat, present in person or by proxy, may adjourn the Annual Meeting from time to time without notice or other announcement until a quorum is present or represented. Assuming the presence of a quorum, the affirmative vote of a plurality of votes cast is required for the

election of each of the nominees for director. A majority of the votes represented and entitled to vote at the Annual Meeting will be required for the approval of all other matters to be voted upon. Abstentions and broker non-votes will each be counted towards the presence of a quorum, but (i) will not be counted as votes cast and, accordingly, will have no effect on the plurality vote required for the election of directors, and (ii) will be counted as votes represented at the Annual Meeting and, accordingly, will have the effect of a vote "against" all other matters to be acted upon.

Proxies in the accompanying form which are properly executed and returned to the Company will be voted at the Annual Meeting in accordance with the instructions contained in such proxies and, at the discretion of the proxy holders, on such other matters as may properly come before the meeting. Where no such instructions are given, the shares will be voted for the election of each of the nominees for director and the ratification of Ernst and Young, LLP as the independent auditor.

A stockholder that intends to present a proposal at the 2005 Annual Meeting of Stockholders for inclusion in the Company's proxy statement and form of proxy relating to such meeting must submit such proposal by August 17, 2005. The proposal must be mailed to the Company's offices at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1.

## SUMMARY

HepaLife Technologies, Inc. is a development stage biotechnology company focused on the identification, development and eventual commercialization of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease.

Currently, HepaLife is concentrating its efforts on creating the first-of-its-kind artificial liver device and developing proprietary in vitro toxicology and pre-clinical drug testing platforms.

## Artificial Liver Device

Through a Cooperative Research and Development Agreement (CRADA) with the United States Department of Agriculture s Agricultural Research Service, HepaLife Technologies is working towards optimizing the hepatic functionality of the patented PICM-19 cell line. The hepatic characteristics of the PICM-19 cell line have been demonstrated to have potential application in the production of an artificial liver device for use by human patients with liver failure.

With 25 million Americans suffering from liver disease, the need for an artificial liver device able to remove toxins and improve immediate and long-term survival results is more critical today than ever before. Limited treatment options, a low number of donor organs, the high price of transplants and follow up costs, a growing base of hepatitis,

alcohol abuse, drug overdoses, and other factors that result in liver disease all clearly indicate a strong need for an artificial liver device.

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.

Under the terms of its CRADA, HepaLife has access to proprietary technology, sophisticated scientific expertise and fully-equipped modern research facilities and office space 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.

In Vitro Toxicology Testing

Hepatotoxicity, or liver damage caused by medications and other chemical compounds, is the single most common reason leading to drug withdrawal or refusal of drug approval by the Food and Drug Administration (FDA). In fact, about one third of all drugs fail pre-clinical or clinical trials due to the toxic nature of the compounds being tested, costing pharmaceutical companies around \$2 billion annually on such toxicity-related drug failures.

With the cost to develop an FDA approved drug approaching \$1 billion and taking 10 to 15 years, a 10% improvement in predicting failures before clinical trials could save \$100 million in development costs per drug. Despite efforts to develop better methods, most of the tools used for toxicology and human safety testing are decades old.

Resulting in part from the limitations of current testing methodology, safety problems are often discovered only during clinical trials, and unfortunately, sometimes after marketing. Examples of recent post-market discoveries include Accolate (asthma drug), Duract (analgesic and anesthetic) and Rezulin (diabetes), all of which were linked to liver damage.

The patented PICM-19 liver stem cell line, concurrently being tested for use in an artificial liver device by HepaLife, can differentiate into either hepatocytes or bile duct cells (two key cell types of the liver) and synthesize liver specific proteins such as albumin and transferrin, as well as display enhanced liver-specific functions such as ureagenesis and

cytochrome P450 activity. As a result, HepaLife, using the patented PICM-19 cell line, is developing proprietary in vitro toxicological and pre-clinical drug testing platforms that will more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

At present, the Company does not have commercial products intended to diagnose, treat, cure or prevent any disease. The statements contained in this proxy regarding ongoing research and development, and results attained by the Company to-date, have not been evaluated by the Food and Drug Administration.

The Company's 2004 Annual Report provides a review of our operations during the past year.

The following is a brief summary of certain information contained elsewhere in this Proxy Statement. This summary is not intended to be complete and is qualified in all respects by reference to the detailed information appearing elsewhere in this Proxy Statement and the exhibit hereto.

## THE MEETING

## Date, Time and Place of the Annual Meeting

The Annual Meeting of HepaLife Technologies, Inc. is scheduled to be held on September 7, 2005, at 1:00 p.m. (local time) at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1.

#### **Record Date**

Only holders of record of shares of Common Stock at the close of business on June 30, 2005, are entitled to receive notice of and to vote at the Annual Meeting.

## **Vote Required**

Assuming the presence of a quorum, the affirmative vote of a plurality of votes cast is required for the election of each of the nominees for director. A majority of the votes cast with a quorum present at the Annual Meeting will be required for the approval of all other matters to be voted upon.

#### Accountants

Ernst and Young, LLP has been selected by the Company to act as its independent auditor for 2005. It is not expected that the representatives of Ernst and Young, LLP will attend the Annual Meeting or be available to answer questions from the stockholders.

#### Recommendations

THE BOARD OF DIRECTORS OF THE COMPANY UNANIMOUSLY RECOMMENDS THAT THE COMPANY'S STOCKHOLDERS VOTE FOR EACH OF THE NOMINEES FOR DIRECTOR ("PROPOSAL 1") AND VOTE FOR THE RATIFICATION OF THE APPOINTMENT OF ERNST AND YOUNG, LLP, AS THE COMPANY'S INDEPENDENT AUDITOR FOR THE FISCAL YEAR ENDING DECEMBER 31, 2005 ("PROPOSAL 2").

**PROPOSAL NO. 1:** 

#### **ELECTION OF BOARD MEMBERS**

Nominees

The Company's Board of Directors is currently comprised of three directors. Each of the nominees is presently a director of the Company. If so directed in the enclosed proxy, the persons named in such proxy will vote the shares represented by such proxy for the election of the following named nominees for the office of director of the Company, to hold office until next annual meeting of the stockholders or until their respective successors shall have been duly elected and shall have qualified.

## **Information Concerning Nominees**

Name Age **Position** Director/Officer Since Arian Soheili 38 President and CEO September 2003 Harmel S. Rayat 44 Treasurer, Secretary & Director December 2000 Jasvir S. Kheleh 31 Director November 2003

The Board of Directors does not contemplate that any of the above-named nominees for director will refuse or be unable to accept election as a director of the Company, or be unable to serve as a director of the Company. Should any of them become unavailable for nomination or election or refuse to be nominated or to accept election as a director of the Company, then the persons named in the enclosed form of proxy intend to vote the shares represented in such proxy for the election of such other person or persons as may be nominated or designated by the Board of Directors. No nominee is related by blood, marriage, or adoption to another nominee or to any executive officer of the Company or its subsidiaries or affiliates.

Assuming the presence of a quorum, each of the nominees for director of the Company requires for his election the approval of a plurality of the votes cast by the shares of Common Stock entitled to vote at the Annual Meeting.

The Board of Directors regard all of the individuals being nominated to the Board as extremely competent professionals with many years of experience in different fields of endeavor, including sales and marketing, management, healthcare, and corporate finance and development. The Board feels that this collective base of experience and knowledge is crucial in the overall development of the Company's business.

## **Information Concerning Current Officers and Directors**

The following narrative describes the positions held by the Company's current officers and directors. During 2004, each board member attended at least 75% of the board meetings that were held while they were in office.

ARIAN SOHEILI, (Age 38). CEO, President, Director. Mr. Soheili has a Bachelor s degree in Business Administration from Simon Fraser University and over 15 years of industry and public practice experience with Grant Thornton, Deloitte and Touche, and others. At Deloitte and Touche, Mr. Soheili was responsible for providing IT solutions to small to mid-size businesses. In 1999, Mr. Soheili launched Cantatus Systems Group, Inc., a firm that specializes in enterprise solutions, technology infrastructure and system integration services. Mr. Soheili joined the Company as a director and its President and Chief Executive Officer on September 22, 2003.

JASVIR S. KHELEH, (Age 31). Director. Mr. Jasvir S. Kheleh received his Diploma in Financial Management majoring in Finance from the British Columbia Institute of Technology (BCIT) in June 1995. In September, 1995 Mr. Kheleh joined Canada Trust, a subsidiary of the Toronto-Dominion Bank s, TD Bank Financial Group. Initially chartered in 1855, TD is headquartered in Toronto, Canada with more than 51,000 employees and \$300 billion (cdn) in assets. In June, 1996 Mr. Kheleh joined the nation s largest credit union institution, Vancity (Vancouver City Savings Credit Union) and was promoted to Financial Services Manager. Mr. Kheleh joined the Company as a Director on November 19, 2003.

HARMEL S. RAYAT, (Age 44). Secretary, Treasurer, Director. Mr. Rayat has been in the venture capital industry since 1981. Between January 1993 and April 2001, Mr. Rayat served as the president of Hartford Capital Corporation, a company that provided financial consulting services to emerging growth corporations. From April 2001 through January 2002, Mr. Rayat acted as an independent consultant advising small corporations. Since January 2002, Mr. Rayat has been president of Montgomery Asset Management Corporation, a privately held firm providing financial consulting services to emerging growth corporations. Mr. Rayat is also a Director of Entheos Technologies, Inc., Enterprise Technologies Corporation and eDeal.net, Inc. Mr. Rayat has served as a Director of the Company since December 4, 2000.

On October 23, 2003, Mr. Harmel S. Rayat, EquityAlert.com, Inc., Innotech Corporation and Mr. Bhupinder S. Mann, a part-time employee of the Company, collectively the respondents, consented to a cease-and-desist order pursuant to Section 8A of the Securities Act of 1933. Without admitting or denying the findings of the Securities and Exchange Commission related to the public relation and stock advertising activities of EquityAlert.com, Inc. and Innotech Corporation, the respondents agreed to cease and desist from committing or causing any violations and any future violations of Section 5(a) and 5(c) of the Securities Act of 1933. EquityAlert.com, Inc. and Innotech Corporation agreed to pay disgorgement and prejudgment interest of \$31,555.14. On August 8, 2000, Mr. Harmel S. Rayat and EquityAlert.com, Inc., without admitting or denying the allegations of the Securities and Exchange Commission that EquityAlert.com, Inc did not disclose certain compensation received by it in connection with stock advertisements and promotions, consented to the entry of a permanent injunction enjoining them from violating Section 17(b) of the Securities Act of 1933; in addition, each agreed to pay a civil penalty of \$20,000.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, officers and persons who own more than 10 percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("the Commission"). Directors, officers and greater than 10 percent beneficial owners are required by applicable regulations to furnish the Company with copies of all forms they file with the Commission pursuant to Section 16(a). Other than Mr. Harmel S. Rayat, the Company is not aware of any beneficial owner of more than 10 percent of its registered Common Stock for purposes of Section 16(a).

Based solely upon a review of the copies of the forms furnished to the Company, the Company believes that during fiscal 2004 all filing requirements applicable to its directors and executive officers were satisfied.

## **Director Compensation**

Directors of the Company are a paid a stipend of \$250 per month, plus \$100 for each Directors meeting attended. The President of the Company, who is also a Director, receives a monthly stipend of \$350, plus \$100 for each Directors meeting attended. All Directors are reimbursed for any out-of-pocket meeting expenses.

## THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF EACH OF THE INDIVIDUALS NOMINATED FOR ELECTION AS A DIRECTOR.

## **PROPOSAL NO. 2:**

## THE RATIFICATION OF THE APPOINTMENT OF ERNST & YOUNG, LLP.

#### AS THE COMPANY S INDEPENDENT AUDITOR

The Board of Directors has selected Ernst and Young, LLP as independent auditors for the Company for the fiscal year ending December 31, 2005, subject to ratification of the selection by shareholders. Ernst and Young, LLP has served as independent public accountants for the Company since May 5, 2005, prior to which the firm of Moore Stephens Ellis Foster Ltd., (which merged with Ernst and Young, LLP on May 5, 2005) served as the Company's independent public accountants from January 12, 2004.

To the knowledge of the Company, at no time has Ernst and Young, LLP had any direct or indirect financial interest in or any connection with the Company or any of its subsidiaries other than in connection with services rendered to the Company as described below.

It is not expected that the representatives of Ernst and Young, LLP or any other auditors will attend the Annual Meeting. Ernst and Young, LLP has not indicated their desire to make a statement. They will respond to written questions submitted to the Company.

During and for the year ended December 31, 2004, Moore Stephens Ellis Foster Ltd. provided the following audit, audit-related and other professional services for the Company. The services were as follows:

the audit of the annual financial statements included in the Company s Form 10-KSB;

Consultation in connection with various tax and accounting matters; and

Certain other professional services.

The cost of providing these services during and for the year ended December 31, 2004, by specified categories, were as follows:

Audit Fees: \$7,686 These fees covered the audit of the Company s annual financial statements.

Financial Information Systems Design and Implementation Fees: None

All Other Fees: \$0 These fees covered services principally involving internal audit support and income tax consulting.

# THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE RATIFICATION OF THE APPOINTMENT OF ERNST AND YOUNG, LLP AS THE COMPANY'S INDEPENDENT AUDITOR.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of June 30, 2005, the beneficial ownership of the Company's Common Stock by each director and executive officer of the Company and each person known by the Company to beneficially own more than 5% of the Company's Common Stock outstanding as of such date and the executive officers and directors of the Company as a group.

Number of Shares

Person or Group

of Common Stock

Percent

Harmel S. Rayat (1)

46,463,056

68%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Harmel S. Rayat (2)

7,000,000

11%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Arian Soheili

0

0%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Jasvir Kheleh

## 0

0%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Directors and Executive Officers

53,463,056

79%

as a group (3 persons)

(1) Includes 3,203,194 shares held by Tajinder Chohan, Mr. Harmel S. Rayat's wife. Additionally, other members of Mr. Rayat's family hold shares and share purchase warrants. Mr. Rayat disclaims beneficial ownership of the shares and share purchase warrants beneficially owned by his wife and other family members.

(2) Includes 5,500,000 stock options granted on February 10, 2003 and 1,500,000 stock options granted on August 27, 2003, which may be acquired pursuant to options granted and exercisable under the Company's stock option plans.

## Voting Intentions of Certain Beneficial Owners and Management

The Company's directors and officers have advised that they will vote the 46,463,056 shares owned or controlled by them FOR each of the Proposals in this Proxy Statement. These shares represented 68% of the outstanding Common Stock of the Company as of June 30, 2005.

#### **Remuneration and Executive Compensation**

The following table shows, for the three-year period ended December 31, 2004, the cash compensation paid by the Company, as well as certain other compensation paid or accrued for such year, to the Company's Chief Executive Officer and the Company's other most highly compensated executive officers. Except as set forth on the following table, no executive officer of the Company had a total annual salary and bonus for 2004 that exceeded \$100,000.

#### **Summary Compensation Table**

Securities

Underlying

Name and

		uyar i m	ING. TEL ALITE TEOLINOLOGIES ING - TOTTI DEL 14A
Options			
All Other			
Principal Position		Year	<u>Salary</u>
Bonus	Other		
Granted			
Compensat	tion		
Harmel S.	Rayat (1)		
2004			
\$0			
\$0			
\$3,500			
0			
\$0			
Secretary,	Treasurer,		
2003			
\$27,000			
\$0			
\$0			
1,500,000			
\$0			
Director			
2002			
\$144,000			
02			

\$0	
5,500,000	
\$0	
Arian Soheili	
2004	
\$0	
\$0	
\$2,500	
0	
\$0	
CEO, President,	
2003	
\$0	
\$0	
\$1,150	
0	
\$0	
Director	
2002	
\$0	
\$0	

\$0

0	
\$0	
Jasvir Kheleh,	
2004	
\$0	
\$0	
\$3,500	
0	
\$0	
Director	
2003	
\$0	
\$0	
\$350	
0	
\$0	
2002	
\$0	
\$0	
\$0	
0	
\$0	

(1) During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable-related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

## Stock Option Grants in Last Fiscal Year

Shown below is further information regarding employee stock options awarded during 2004 to the named officers and directors:

Number of % of Total Securities **Options Granted** Underlying to Employees Exercise Expiration <u>Name</u> **Options** <u>in 2004</u> Price (\$/sh) Date Arian Soheili

0

0

n/a	
n/a	
Harmel Rayat	
0	
0	
n/a	
n/a	
Jasvir Kheleh	
0	
0	
n/a	
n/a	

## Aggregated Option Exercises during Last Fiscal Year and Year End Option Values

The following table shows certain information about unexercised options at year-end with respect to the named officers and directors:

Common Shares Underlying Unexercised

Value of Unexercised In-the-money

Options on December 31, 2004

Options on December 31, 2004

<u>Name</u>

Exercisable

Unexercisable		
Exercisable		
Unexercisable		
Arian Soheili		
0		
0		
0		
0		
Harmel Rayat		
5,166,667		
1,833,333		
20,201,668		
7,168,332		
Jasvir Kheleh		
0		
0		
0		
0		

## **Related Transactions**

## Management fees

During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

#### Notes Payable

At a Board of Directors meeting held on May 28, 2003, the Company s Board of Directors agreed to accept a loan of up to \$750,000 from a director and major stockholder of the Company. Proceeds from the loan, which will be drawn down on an as needed basis , will be used to fund the Company s research and development commitments, legal and audit fees, ongoing investor and public relations costs and other working capital requirements.

Total unsecured promissory notes issued in 2003 of \$725,000 bearing interest at rates ranging from 7.00% to 7.25% were repaid in 2004 including accrued interest of \$51,500.

On August 27, 2004, the Company drew down \$300,000 from the loan commitment and issued an unsecured promissory note bearing an interest rate of 7.50%, due on August 27, 2005.

Accrued interest as at December 31, 2004 of \$7,187 is included in accounts payable related parties.

In December 2004, the same director and major stockholder of the Company paid \$700,000 in investor relation fees on behalf of the Company. For reimbursement, the Company issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

#### Amounts payable to related parties

Included in accounts payable related parties is \$17,272 (2003 - \$0) payable to various stockholders for expenses incurred on behalf of the Company, of which \$12,595 is payable to the same director and majority shareholder in note b above.

#### Rent Expenses

The Company's office is located at Suite 216, 1628 West 1st Avenue, Vancouver, British Columbia, Canada. These premises are owned by a private corporation of the same director and officer of the Company in note b above. At present, the Company pays no rent. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

#### **Warrants**

All 2,700,000 warrants outstanding as at December 31, 2004 (2003 4,700,000) (see Note 7), are held by unaffiliated family members of the same director and majority stockholder in note b above.

#### **Employment Contracts**

The Company does not have any employment contracts with any of its officers or employees.

## **COPIES OF FORM 10-KSB**

The Company hereby undertakes to provide without charge to each person, including any beneficial owner, to whom a copy of this Proxy Statement has been delivered, on the written request of any such person, a copy of the Company's

most recent Form 10-KSB. Written requests for such copies should be directed to Mr. Harmel S. Rayat, the Secretary of the Company, at Suite 216, 1628 West 1st Avenue, Vancouver, B.C., V6J 1G1.

## **HEPALIFE TECHNOLOGIES, INC.**

216 1628 West 1st Avenue

Vancouver, B.C. V6J 1G1

## **PROXY FOR 2005 ANNUAL MEETING OF STOCKHOLDERS**

## This proxy is solicited on behalf of the Board of Directors of HepaLife Technologies, Inc.

The undersigned, a stockholder of HepaLife Technologies, Inc. (the Company ) hereby constitutes and appoints each of Mr. Jasvir S. Kheleh and Mr. Arian Soheili the attorney, agent and proxy of the undersigned, with full power of substitution, for and in the name, place and stead of the undersigned, to vote and act with respect to all of shares of the Common Stock of the Company standing in name of the undersigned or in respect of which the undersigned is entitled to vote, with all powers of the undersigned would process if personally present at such meeting upon the following matters, and otherwise in his discretion:

## FOR AGAINST ABSTENTION

ITEM 1.

To elect directors to serve until the next annual

meeting of stockholders or until their successors

are elected and have qualified.

Mr. Arian Soheili

[]][]

[ ]

Mr. Jasvir S. Kheleh

[] []

[ ]

Mr. Harmel S. Rayat

[ ] [ ]

[ ]

ITEM 2.

To ratify the appointment of Ernst and Young, LLP

[][]

[ ]

for the fiscal year ending December 31, 2005

## ITEM 3.

To transact any such other business as may

[]][]

[ ]

properly come before the meeting or an

adjournment (s) therefore.

If no direction is indicated, this proxy will be voted in the discretion of the proxy holder. Please date, sign and print your name on this proxy exactly as your name appears on your stock certificate and return immediately to the address printed above.

DATED:\_\_\_\_\_

SIGNATURE:\_\_\_\_\_

NO. OF SHARES:\_\_\_\_\_

PRINT NAME:\_\_\_\_\_

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-KSB

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

For the fiscal year ended December 31, 2004

OR

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

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

**Commission File Number 000-29819** 

## **HEPALIFE TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

## **FLORIDA**

(State or other jurisdiction of incorporation)

## <u>58-2349413</u>

(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)

## Common Stock, \$.001 par value per share

Title of Each Class

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 for the past 90 days. Yes [X] No [\_]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB [X]

Revenues for last fiscal year were \$0.00

Aggregate market value of Common Stock, \$0.001 par value, held by non-affiliates of the registrant as of March 29, 2005: \$67,367,997. Number of shares of Common Stock, \$0.001 par value, outstanding as of March 29, 2005: 67,917,832.

Transitional Small Business Disclosure Format: Yes [ ] No [X]

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#### **HEPALIFE TECHNOLOGIES, INC.**

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## PART I

## **ITEM 1. DESCRIPTION OF BUSINESS**

## **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-KSB for the fiscal year ending December 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-KSB 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-KSB. 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. We currently have no commercial products intended to diagnose, treat, prevent or cure any disease. The statements contained in this Form 10-KSB regarding our on going research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration. There can be no assurance that further research and development, and /or whether clinical trial results, if any, will validate and support the results of our preliminary research and studies. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that we will be able to develop commercially viable products on the basis of its technologies. Readers are urged to carefully review and consider the various disclosures made by the Company in this Form 10-KSB 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.

## The Company

HepaLife Technologies, Inc. (the Company or HepaLife ) was incorporated under the laws of the State of Florida on October 21, 1997, with an authorized capital of 100,000,000 shares of common stock, par value of \$0.001 per share and 1,000,000 shares of \$0.10 par value preferred stock, which may be divided into series with the rights and preferences of the preferred stock to be determined by the Board of Directors.

On August 10, 2001, Articles of Amendment to the Articles of Incorporation were filed in the State of Florida to increase the authorized capital stock of the Company to 300,000,000 shares of \$0.001 par value common stock. At a Board of Directors meeting held on April 17th, 2003, the Company s Board of Directors agreed to change the Company s name from Zeta Corporation to HepaLife Technologies, Inc. in order to more accurately describe the Company s business and to amend its Articles of Incorporation to reflect the name change.

## **Description of Business**

HepaLife Technologies, Inc. (www.hepalife.com) is a development stage biotechnology company focused on the identification, development and eventual commercialization of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease.

Currently, HepaLife is concentrating its efforts on creating the first-of-its-kind artificial liver device and developing proprietary in vitro toxicology and pre-clinical drug testing platforms.

#### Artificial Liver Device

Through a Cooperative Research and Development Agreement (CRADA) with the United States Department of Agriculture s Agricultural Research Service, HepaLife Technologies is working towards optimizing the hepatic functionality of the patented PICM-19 cell line. The hepatic characteristics of the PICM-19 cell line have been demonstrated to have potential application in the production of an artificial liver device for use by human patients with liver failure.

With 25 million Americans suffering from liver disease, the need for an artificial liver device able to remove toxins and improve immediate and long-term survival results is more critical today than ever before. Limited treatment options, a low number of donor organs, the high price of transplants and follow up costs, a growing base of hepatitis, alcohol abuse, drug overdoses, and other factors that result in liver disease all clearly indicate a strong need for an artificial liver device.

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.

Under the terms of its CRADA, HepaLife has access to proprietary technology, sophisticated scientific expertise and fully-equipped modern research facilities and office space 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.

In Vitro Toxicology Testing

Hepatotoxicity, or liver damage caused by medications and other chemical compounds, is the single most common reason leading to drug withdrawal or refusal of drug approval by the Food and Drug Administration (FDA). In fact, about one third of all drugs fail pre-clinical or clinical trials due to the toxic nature of the compounds being tested, costing pharmaceutical companies around \$2 billion annually on such toxicity-related drug failures.

With the cost to develop an FDA approved drug approaching \$1 billion and taking 10 to 15 years, a 10% improvement in predicting failures before clinical trials could save \$100 million in development costs per drug. Despite efforts to develop better methods, most of the tools used for toxicology and human safety testing are decades old.

Resulting in part from the limitations of current testing methodology, safety problems are often discovered only during clinical trials, and unfortunately, sometimes after marketing. Examples of recent post-market discoveries include Accolate (asthma drug), Duract (analgesic and anesthetic) and Rezulin (diabetes), all of which were linked to liver damage.

Hepatocytes, the major cell type comprising of the liver, perform the important task of metabolizing or detoxifying drug compounds that enter the body. This is accomplished primarily through cytochrome P450 enzymes that are abundantly expressed in hepatocytes. Therefore, hepatocytes grown in vitro have application for the rapid screening of multiple drug candidates to predict their potential liver toxicity and liver-specific pharmacological characteristics prior to clinical testing.

The patented PICM-19 liver stem cell line, concurrently being tested for use in an artificial liver device by HepaLife, can differentiate into either hepatocytes or bile duct cells (two key cell types of the liver) and synthesize liver specific proteins such as albumin and transferrin, as well as display enhanced liver-specific functions such as ureagenesis and cytochrome P450 activity. As a result, HepaLife, using the patented PICM-19 cell line, is developing proprietary in vitro toxicological and pre-clinical drug testing platforms that will more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

At present, the Company does not have commercial products intended to diagnose, treat, cure or prevent any disease. The statements contained in this press release regarding ongoing research and development, and results attained by the Company to-date, have not been evaluated by the Food and Drug Administration.

## Liver Disease

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

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).

On January 3, 2005, the National Institutes of Health (NIH) released a comprehensive plan (Action Plan for Liver Disease Research) addressing the burden of liver disease in the United States and directing NIH funding and research resources towards the prevention, diagnosis, and management of liver and biliary diseases.

Prepared by a consortium of 17 NIH institutes and 250 liver disease experts, including clinical researchers, doctors, academicians and concerned lay persons, the purpose of the NIH Action Plan is to identify areas of scientific opportunity and then provide funding and research resources for advancing research on liver and biliary diseases, one of the leading causes of death in America. According to the Action Plan, an estimated one quarter of Americans will suffer from a liver or biliary disease at some point in their lifetime.

In a subsection of the Action Plan (Complications of Liver Disease; Prevention of Acute Liver Failure) the NIH report states, In the area of acute liver failure, the primary goals of research should be in developing means to prevent acute liver failure and ameliorate its course .Most helpful would be an artificial or bioartificial liver assist device that could be used to sustain patients and serve as a bridge to liver transplantation, which is the only effective treatment that is currently available for fulminant hepatic failure.

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

Adverse drug reactions are an increasingly important clinical problem in medicine today and rank among the ten most common causes of death (Hepatotoxicity Clinical Research Network). While drug induced liver injury occurs in all age groups, a greater percentage occurs in the elderly, where five out of six persons 65 and older are taking at least one medication and almost half are of the elderly take three or more.

With almost half of the general population now taking at least one prescription drug and one person in every six taking three or more (Centers for Disease Control and Prevention, December 2, 2004), the incidence of drug side effects and other related health problems reported to the FDA has reached all time highs, with 422,500 cases reported in 2004, up 14% from the previous year.

Even common 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.

#### <u>Hepatitis</u>

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 the first-of-its-kind artificial liver device and developing proprietary in vitro toxicology and pre-clinical drug testing platforms.

#### 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 for use as an in vitro liver model, for their use in an artificial liver device, and for their use in the in vitro assay of metabolic, toxic, or carcinogenic responses. Concurrent with these efforts and those listed below, bioengineering investigations on the cell culture hardware of an artificial liver device are ongoing.

Develop feeder-cell-independent and serum-free medium cell culture systems allowing the growth and differentiation of ARS-PICM-19 cells, or subclones or subpopulations of the ARS-PICM-19 cells, under defined conditions.

2)

Develop spheroid cultures of PICM-19 cells without STO feeder cells and testing of rotating cell culture system (RCCS) for production and maintenance of spheroids.

# 3)

Investigate effects of accessory cells obtained from pig liver on ARS-PICM-19 growth, differentiation, and metabolic function.

# 4)

Assay ARS-PICM-19 cells and spheroids for liver specific functions by measuring P450 activity, -glutamyltranspeptidase activity, urea production, and ammonia clearance.

# 5)

Assay ARS-PICM-19 liver specific protein synthesis and secretion by electrophoretic, immunochemical, or mass spectrophotometric techniques.

# 6)

Develop and test, by in vitro assay, flow-through bioreactors that enable the growth, differentiation, and maintenance of metabolic function of the ARS-PICM-19 cell line, or its derivative cell lines, over long term culture (1-3 months).

# 7)

Develop and test multi-well cell culture formats for the in vitro assay of the effects of various test compounds on the metabolism and viability of ARS-PICM-19-derived hepatocytes or bile ductules.

# 8)

Genetically engineer ARS-PICM-19 cells to create derivative cell lines containing gene reporter constructs, e.g., green fluorescent protein (GFP) based constructs, so that GFP expression is linked to various cell metabolic responses or

stimulation of various cell signal transduction pathways.

9)

Develop cell transformation assay formats to demonstrate and enable the utilization of the ARS-PICM-19 cell line for the study of mutagenic or carcinogenic processes.

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.

# **Employees**

At December 31, 2004, HepaLife had 1 full-time employee and 3 part-time employees. In addition, through the Company s Cooperative Research and Development Agreement, 1 USDA full time research scientist and 2 part-time senior research scientists. To the best of the Company's knowledge, none of the Company's officers or directors is bound by restrictive covenants from prior employers. None of the Company's employees are represented by labor unions or other collective bargaining groups. We consider relations with our employees to be good. We plan to retain and utilize the services of outside consultants for additional research, testing, regulatory and legal compliance and other services.

# **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 \$3,747,771 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 2007, 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 March 29, 2005, our officers and board members own 68% of the 67,917,832 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.

# **ITEM 2. DESCRIPTION OF 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, the Company pays no rent. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

The Company s ongoing research and development work is conducted on at two USDA laboratories, the Growth Biology Laboratory and the Biotechnology and Germplasm Laboratory, both located at US Department of Agriculture, ARS, BARC-East, Bldg. 200, Room 202 and Room 13, Beltsville MD 20705.

# **ITEM 3. LEGAL PROCEEDINGS**

The Company is not party to any current legal proceedings.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of the security holders in the fourth quarter of 2004. It is our intention to schedule a shareholder s meeting to elect directors and transact any additional business in the second or third quarter of 2005.

#### PART II

#### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

The Company's Common Stock is listed on the OTC Bulletin Board under the symbol "HPLF". The following table sets forth the high and low sale prices for the periods indicated:

High
Low
First Quarter 2003
\$0.70
\$0.20
Second Quarter 2003
\$1.77
\$0.44
Third Quarter 2003
\$2.18
\$1.51
Fourth Quarter 2003
\$3.59
\$1.74
First Quarter 2004
\$3.62
\$2.55
Second Quarter 2004
\$2.99
\$1.47
Third Quarter 2004

\$2.91 \$1.95 Fourth Quarter 2004 \$5.80 \$2.06 January 1, 2005-March 29, 2005 \$4.98 \$2.25

As of December 31, 2004, there were approximately 58 stockholders of record of the Company's Common Stock. We are engaged in a highly dynamic industry, which often results in significant volatility of our common stock price.

# **Dividend Policy**

We have never paid cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and other factors as the Board of Directors deems relevant. Our Board of Directors has the right to authorize the issuance of preferred stock, without further shareholder approval, the holders of which may have preferences over the holders of the Common Stock as to payment of dividends.

# Securities Authorized for Issuance Under Equity Compensation Plans

Number of securities

remaining available for

Number of Securities to be

Weighted-average exercise

future issuance under
issued upon exercise of
price of outstanding
equity compensation plans
outstanding options,
options, warrants and
(excluding securities
warrants and rights
rights
reflected in column (a))
Plan Category
(a)
(b)
(c)

Equity compensation plans

approved by security holders

13,833,000

\$0.39

26,925,000

Equity compensation plans not

approved by security holders

Total

13,833,000

\$0.39

26,925,000

# ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

The following discussion should be read in conjunction with the financial statements and notes thereto included in Item 7 of this Form 10-KSB. Except for the historical information contained herein, the discussion in this Annual Report on Form 10-KSB contains certain forward-looking statements that involve risk and uncertainties, such as statements of the Company's plans, objectives, expectations and intentions as of the date of this filing. The cautionary statements made in this document should be read as being applicable to all related forward-looking statements wherever they appear in this document. The Company's actual results could differ materially from those discussed here. Factors that could cause differences include those discussed in "Risk Factors", as well as discussed elsewhere herein.

# **Overview**

HepaLife Technologies, Inc. (www.hepalife.com) is a development stage biotechnology company focused on the identification, development and eventual commercialization of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease.

Currently, HepaLife is concentrating its efforts on creating the first-of-its-kind artificial liver device and developing proprietary in vitro toxicology and pre-clinical drug testing platforms.

# **Results of Operations**

Revenues: The Company is a development stage company and has not generated any revenues since inception, October 21, 1997

General and Administrative Expenses: During 2004, the Company incurred \$1,285,988 in general and administrative expenses, an increase of 21% over 2003 expenses of \$1,062,270. The increase is primarily attributable to costs related to the Company s ongoing shareholder and investor relations program for the purposes of increasing industry and investor awareness and enhancing the Company s image in the investment and biotechnology fields.

Interest Income: Interest income was \$1,921 and \$947 for the years ended December 31, 2004, and 2003, respectively. Interest earned in the future will be dependent on Company funding cycles and prevailing interest rates.

Research and Development Expenses: During 2004, the Company incurred \$151,546 in research and development expenses, compared to \$41,400 in 2003. These expenses were incurred pursuant to a Cooperative Research and Development Agreement with the United States Department of Agriculture s Agricultural Research Service. The research and development costs were expensed as the future economic benefits are uncertain and therefore, cannot be measured with a reasonable degree of certainty. In other words, there is no indication that an economic resource has been created.

Provision for Income Taxes: As of December 31, 2004, the Company's accumulated deficit was \$3,747,771 and as a result, there has been no provision for income taxes to date.

Net Income: For the year ended December 31, 2004, the Company recorded a net loss of \$1,435,534, compared to net loss of \$1,103,670 for the same period in 2003. The increase in net loss of 30% is a result of an increase in general and administrative expenses as mentioned above, as well as increased research and development costs.

# Liquidity and Capital Resources

At December 31, 2004, the Company had a cash balance of \$613,523, compared to a cash balance of \$312,201 at December 31, 2003.

During 2004, the Company used \$1,364,209 of net cash from operating activities, as compared to \$1,022,501 of net cash in 2003.

Net cash provided by financing activities was \$1,666,620 for 2004 compared to \$1,306,100 for 2002. The Company has financed its operations primarily from cash on hand, through loans from shareholders and proceeds from stock option and warrant exercises.

#### Cooperative Agreement

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

On May 24, 2004, HepaLife Technologies, Inc. agreed to extend its CRADA with the USDA s ARS for an additional three years through September 30, 2007.

ARS will receive a total of \$807,828.00 in funds to study experimental culture conditions for the ARS-PICM-19 cell line, its derivative cell lines, or other pig epiblast-derived liver cell lines (as described under ARS patent #5,532,156, Hepatocyte Cell Line Derived from the Epiblast of Pig Blastocysts ) so as to optimize their hepatocyte functions for

use as an in vitro liver model, for their use in an artificial liver device, and for their use in the in vitro assay of metabolic, toxic, or carcinogenic responses. Specific project objectives are the following:

# 1)

Develop feeder-cell-independent and serum-free medium cell culture systems allowing the growth and differentiation of ARS-PICM-19 cells, or subclones or subpopulations of the ARS-PICM-19 cells, under defined conditions.

# 2)

Develop spheroid cultures of PICM-19 cells without STO feeder cells and testing of rotating cell culture system (RCCS) for production and maintenance of spheroids.

# 3)

Investigate effects of accessory cells obtained from pig liver on ARS-PICM-19 growth, differentiation, and metabolic function.

# 4)

Assay ARS-PICM-19 cells and spheroids for liver specific functions by measuring P450 activity, -glutamyltranspeptidase activity, urea production, and ammonia clearance.

# 5)

Assay ARS-PICM-19 liver specific protein synthesis and secretion by electrophoretic, immunochemical, or mass spectrophotometric techniques.

#### 6)

Develop and test, by in vitro assay, flow-through bioreactors that enable the growth, differentiation, and maintenance of metabolic function of the ARS-PICM-19 cell line, or its derivative cell lines, over long term culture (1-3 months).

# 7)

Develop and test multi-well cell culture formats for the in vitro assay of the effects of various test compounds on the metabolism and viability of ARS-PICM-19-derived hepatocytes or bile ductules.

#### 8)

Genetically engineer ARS-PICM-19 cells to create derivative cell lines containing gene reporter constructs, e.g., green fluorescent protein (GFP) based constructs, so that GFP expression is linked to various cell metabolic responses or stimulation of various cell signal transduction pathways.

9)

Develop cell transformation assay formats to demonstrate and enable the utilization of the ARS-PICM-19 cell line for the study of mutagenic or carcinogenic processes.

Hepalife Technologies will provide funds for the salary of one post-doctoral researcher, one support scientist, and one technician for a period of three years and funds for the associated laboratory supplies and professional activities involved with conducting the CRADA objectives under the following payment schedule:

(1)

\$65,422.80 on or before August 1, 2004;

(2)

\$65,422.80 on or before November 1, 2004;

(3)

\$65,422.80 on or before February 1, 2005;

(4)

\$65,422.80 on or before May 1, 2005;

(5)

\$65,422.80 on or before August 1, 2005;

(6)

\$65,422.80 on or before November 1, 2005;

(7)

\$65,422.80 on or before February 1, 2006;

(8)

\$65,422.80 on or before May 1, 2006;

(9)

\$65,422.80 on or before August 1, 2006;

(10)

\$65,422.80 on or before November 1, 2006

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.

Plan of Operation

Through a Cooperative Research and Development Agreement with the United States Department of Agriculture s Agricultural Research Service, the Company is working towards optimizing the function of a patented cell line and applying this technology to the development of extra corporeal liver assist device, as well as in vitro toxicology testing

to more accurately determine the potential toxicity and metabolism of new pharmacological compounds.

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, 2005, 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 business, the Company expects to incur losses as the Company conducts its ongoing research and product development programs. We will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for any possible acquisitions or new technologies, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased losses from operations. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

# Going Concern

The Company has incurred net operating losses since inception. The Company faces all the risks common to companies in their early stages of development, including under capitalization and uncertainty of funding sources, high initial expenditure levels, uncertain revenue streams, and difficulties in managing growth. The Company s recurring losses raise substantial doubt about its ability to continue as a going concern. The Company s financial statements do not reflect any adjustments that might result from the outcome of this uncertainty. The Company expects to incur losses from its business operations and will require additional funding during 2005. The satisfaction of our cash hereafter will depend in large part on the Company s ability to successfully raise capital from external sources to pay for planned expenditures and to fund operations.

# Related Party Transactions

# (a) Management fees

During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

# (b) Notes Payable

At a Board of Directors meeting held on May 28, 2003, the Company s Board of Directors agreed to accept a loan of up to \$750,000 from a director and major stockholder of the Company. Proceeds from the loan, which will be drawn down on an as needed basis , will be used to fund the Company s research and development commitments, legal and audit fees, ongoing investor and public relations costs and other working capital requirements.

Total unsecured promissory notes issued in 2003 of \$725,000 bearing interest at rates ranging from 7.00% to 7.25% were repaid in 2004 including accrued interest of \$51,500.

On August 27, 2004, the Company drew down \$300,000 from the loan commitment and issued an unsecured promissory note bearing an interest rate of 7.50%, due on August 27, 2005.

Accrued interest as at December 31, 2004 of \$7,187 is included in accounts payable related parties.

In December 2004, the same director and major stockholder of the Company paid \$700,000 in investor relation fees on behalf of the Company. For reimbursement, the Company issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

# (c) Amounts payable to related parties

Included in accounts payable related parties is \$17,272 (2003 - \$nil) payable to various stockholders for expenses incurred on behalf of the Company, of which \$12,595 is payable to the same director and majority shareholder in note b above.

#### (d) Rent Expenses

The Company's office is located at Suite 216, 1628 West 1st Avenue, Vancouver, British Columbia, Canada. These premises are owned by a private corporation of the same director and officer of the Company in note b above. At present, the Company pays no rent. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

#### (e) Warrants

All 2,700,000 warrants outstanding as at December 31, 2004 (2003 4,700,000) (see Note 7), are held by unaffiliated family members of the same director and majority stockholder in note b above.

#### 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 sability 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.

# **ITEM 7. FINANCIAL STATEMENTS**

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#### **MOORE STEPHENS**

# ELLIS FOSTER LTD.

#### CHARTERED ACCOUNTANTS

1650 West 1st Avenue

Vancouver, BC Canada V6J 1G1

Telephone: (604) 737-8117 Facsimile: (604) 714-5916

Website: <u>www.ellisfoster.com</u>

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

HEPALIFE TECHNOLOGIES, INC.

(formerly Zeta Corporation)

(A development stage company)

We have audited the balance sheet of **Hepalife Technologies**, **Inc.** (formerly Zeta Corporation) (A development stage company) ( the Company ) as at December 31, 2004 and the related statements of stockholders equity (deficiency), operations and cash flows for the years ended December 31, 2004 and 2003 and the cumulative data from October 21, 1997 (inception) to December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The Company's financial statements for the period from October 21, 1997 (inception) to December 31, 2003, expressed an unqualified opinion, has been furnished to us. Our opinion, insofar as it relates to the amounts included for cumulative data from October 21, 1997 (inception) to December 31, 2002, is based solely on the report of the other auditors.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, these financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2004 and the results of its operations and its cash flows for the years ended December 31, 2004 and 2003 and the cumulative data from October 21, 1997 (inception) to December 31, 2004 in conformity with generally accepted accounting principles in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company is a development stage company since inception on October 21, 1997, and has incurred significant recurring net losses since then resulting in a substantial accumulated deficit, which raise substantial doubt about its ability to continue as a going concern. The Company is devoting substantially all of its present efforts in establishing its business. Management s plans regarding these matters are also disclosed in Note 1 to the financial statements. The ability to meet its future financing requirements and the success of future operations cannot be determined at this time. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Vancouver, Canada

MOORE STEPHENS ELLIS FOSTER LTD.

March 15, 2005

Chartered Accountants

MSEFA partnership of incorporated professionals

An independently owned and operated member of Moore Stephens North America Inc., a member of Moore Stephens International Limited

- members in principal cities throughout the world

# **HEPALIFE TECHNOLOGIES, INC.**

(formerly Zeta Corporation)

(A development stage company)

Balance Sheet

December 31, 2004

(Expressed in U.S. Dollars)

2004

\$

# ASSETS

# **Current assets**

Cash and cash equivalents

613,523

# **Total current assets**

613,523

Equipment, net

828

# **Total assets**

614,351

# LIABILITIES AND STOCKHOLDERS' EQUITY

Liabilities

# **Current liabilities**

Accounts payable and accrued liabilities

100,243

Accounts payable - related parties

53,059

Notes payable - related party

1,000,000

# **Total current liabilities**

\$

1,153,302

# Stockholders' Equity

Preferred stock: \$0.10 par value; Authorized: 1,000,000

Issued and outstanding: None

Common stock: \$0.001 par value; Authorized: 300,000,000

Issued and outstanding: 67,817,832

67,818

-

Additional paid in capital

# 3,141,002

Loss accumulated during the development stage

(3,747,771)

Total stockholders' equity

(538,951)

Total liabilities and stockholders' equity

614,351

**Commitments and contingencies** 

The accompanying notes are an integral part of these financial statements.

# HEPALIFE TECHNOLOGIES, INC.

(formerly Zeta Corporation) (A development stage company)

Statements of Stockholders' Equity (Deficiency) (Expressed in U.S. Dollars)

		Loss	Total
		accumulated	stock-
	Additional	during	holders'
Common shares	paid-in	development	equity

\$

	Shares	Amount	capital	stage	(deficiency)
Common stock issued for services rendered at \$0.00025 per share, October 21, 1997	12,000,000	\$ 12,000	\$ (9,000)	\$ -	\$ 3,000
Common stock issued for cash at \$0.0625 per share during 1997	1,200,000	1,200	73,800	-	75,000
Comprehensive income Income from inception (October 21,					
1997) to December 31, 1997	-	-	-	42	42
Balance, December 31, 1997	13,200,000	13,200	64,800	42	78,042
Common stock issued for services rendered at \$0. 025 per share, December 15, 1998	16,000,000	16,000	384,000	-	400,000
Comprehensive income (loss) Loss, year ended December 31, 1998	-	-	-	(471,988)	(471,988)
Balance, December 31, 1998	29,200,000	29,200	448,800	(471,946)	6,054
Common stock issued for cash at \$0. 025 per share, March 1999	12,000,000	12,000	288,000	-	300,000
Comprehensive income (loss) Loss, year ended December 31, 1999	-	-	-	(121,045)	(121,045)
Balance, December 31, 1999	41,200,000	41,200	736,800	(592,991)	185,009
Comprehensive income (loss) Loss, year ended December 31, 2000	-	-	-	(80,608)	(80,608)
Balance, December 31, 2000	41,200,000	41,200	736,800	(673,599)	104,401

Balance, December 31, 2000	41,200,000	\$ 41,200	\$ 736,800	\$ (673,599)	\$ 104,401
Conversion of debt to equity at \$0.015					
per share, July 13, 2001	8,933,332	8,933	125,067	-	134,000
Comprehensive income (loss)					
Loss, year ended December 31, 2001	-	-	-	(160,364)	(160,364)
Balance, December 31, 2001	50,133,332	50,133	861,867	(833,963)	78,037
Common stock issued for services at					
\$0.06 per share, April 23, 2002	10,000	10	590	-	600
Conversion of debt to equity at \$0.05					
per share, April 26, 2002	2,160,000	2,160	105,840	-	108,000
Common stock issued for investor relations					
services at \$0.05 per share, July 25 , 2002	2,390,000	2,390	117,110	-	119,500
Conversion of debt to equity at \$0.05 per					
share, December 18, 2002	1,920,000	1,920	94,080	-	96,000
Comprehensive income (loss)					
Loss, year ended December 31, 2002	-	-	-	(375,472)	(375,472)
Balance, December 31, 2002	56,613,332	56,613	1,179,487	(1,209,435)	26,665
Common stock issued pursuant to					
exercise of stock options during the year					
at between \$0.07 to \$2.11					
per share	282,500	283	398,317	-	398,600
Common stock issued pursuant to					
exercise of share purchase warrants in					
November 2003 at \$0.025 per share	7,300,000	7,300	175,200	-	182,500
Comprehensive income (loss)					
•	-	-	-	(1,102,723)	(1,102,723)

Loss, year ended December 31, 2003							
Balance, December 31, 2003	64,195,832	\$	64,196	\$	1,753,004	\$ (2,312,158)	\$ (494,958)
Balance, December 31, 2003	64,195,832	\$	64,196	\$	1,753,004	\$ (2,312,158)	\$ (494,958)
Common stock issued pursuant to exercise of stock options during the year							
at between \$0.07 to \$2.11 per share	1,622,000		1,622		1,339,998		1,341,620
Common stock issued pursuant to exercise of share purchase warrants in December 2004							
at \$0.025 per share	2,000,000		2,000		48,000		50,000
Comprehensive income (loss) Loss, year ended December							
31, 2004 <b>Balance</b> , December 31, 2004	67,817,832	\$	67,818	\$	3,141,002	(1,435,613) \$ (3,747,771)	(1,435,613)
Datance, December 31, 2004	07,017,032	φ	07,010	φ	5,141,002	$\varphi$ (3,141,111)	φ (330,931)

The accompanying notes are an integral part of these financial statements.

# HEPALIFE TECHNOLOGIES, INC.

(formerly Zeta Corporation) (A development stage company)

# Statements of Operations (Expressed in U.S. Dollars)

Cumulative
Amount Since
Inception to
December 31
2004

Year ended Year ended December 31 December 31 2004 2003

General and administrative expenses			
Administrative and general	\$ 222,399	\$ 92,269	\$ 10,302
Depreciation	3,732	261	583
Interest on promissory note	58,687	39,021	19,666
Interest, bank charges and			
foreign exchange loss	2,563	925	792
Professional fees - accounting and			
legal	81,510	12,139	37,506
Management and consulting fees	909,314	9,500	28,500
Salary and benefits	26,352	26,352	-
Shareholder and investor relations	2,096,419	1,016,916	960,003
Transfer agent and filing	6,716	637	4,918
Travel	87,968	87,968	-
	3,495,660	1,285,988	1,062,270
<b>Research and development</b>	284,446	151,546	41,400
	3,780,106	1,437,534	1,103,670
<b>Operating (loss)</b>	(3,780,106)	(1,437,534)	(1,103,670)
Other income			
Interest income	32,335	1,921	947
Net (loss) for the year	\$ (3,747,771)	\$ (1,435,613)	\$ (1,102,723)
Loss per share of common stock			
- basic and diluted		\$ (0.02)	\$ (0.019)
Basic weighted average number			
of common stock outstanding			
- basic and diluted		64,610,777	57,817,305
			· · ·

The accompanying notes are an integral part of these financial statements.

# HEPALIFE TECHNOLOGIES, INC.

(formerly Zeta Corporation)

(A development stage company)

# Statements of Cash Flows (Expressed in U.S. Dollars)

( <b>F</b>	Cumulative Amount Since Inception to December 31 2004	Year ended December 31 2004	Year ended December 31 2003
Cash flows from (used in)			
operating activities			
Net (loss) for the year	\$ (3,747,771)	\$ (1,435,613)	\$ (1,102,723)
Adjustments to reconcile net (loss) to			
net cash used in operating activities:			
- depreciation	3,732	261	583
- common stock issued for services	523,100	-	-
- conversion of debt to equity	338,000	-	-
Changes in non-cash working capital items:			
- increase in accounts payable	100,243	18,084	79,639
- increase in accounts payable - related parties	53,059	53,059	-
Net cash used in operating activities	(2,729,637)	(1,364,209)	(1,022,501)
Cash flows used in			
investing activities			
Purchase of equipment	(4,560)	(1,089)	-
Net cash used in investing activities	(4,560)	(1,089)	-
Cash flows from (used in) financing activities			
Net proceeds from notes payable	1,000,000	275,000	725,000
Proceeds from the sale of common			
stock	2,347,720	1,391,620	581,100
Net cash provided by financing activities	3,347,720	1,666,620	1,306,100
Increase in cash and cash equivalents	613,523	301,322	283,599

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The accompanying notes are an integral part of these financial statements.

## **HEPALIFE TECHNOLOGIES, INC.**

(formerly Zeta Corporation)

(A development stage company)

Notes to Financial Statements

Years Ended December 31, 2004 and 2003

(Expressed in U.S. Dollars)

## 1.

### **Organization and Nature of Operations**

Hepalife Technologies, Inc. (formerly Zeta Corporation) (the Company ) was incorporated under the laws of the State of Florida on October 21, 1997, with an authorized capital of 100,000,000 shares of common stock, par value of \$0.001 per share, and 1,000,000 shares of \$0.10 par value preferred stock, which may be divided into series with the rights and preferences of the preferred stock to be determined by the Board of Directors. On August 10, 2001, Articles of Amendment to the Articles of Incorporation were filed in the State of Florida to increase the authorized capital stock of the Company to 300,000,000 shares of \$0.001 par value common stock.

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 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 since inception resulting in a substantial accumulated deficit and has used substantial amounts of working capital in its operations. In view of these matters, the continued operations of the Company is dependent upon the Company s ability to meet its financing requirements, and the success of its future operations. The Company expects to incur losses as it expands its business and will require additional funding during 2005.

To meet these objectives, the Company plans to seek additional equity and expects to raise funds through a private or public equity investment 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. 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, 2005, however, there can be no assurances to that effect. If adequate funds are not available or not available on acceptable terms, the Company may be (i) unable to fund further research and operating plans, (ii) required to scale back or abandon our research and product development activities, (iii) reduce our workforce, and (iv) license to others products or technologies we would otherwise seek to commercialize ourselves, all of which could have a material adverse effect on our business, results of operations and financial condition. 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.

2.

# **Summary of Significant Accounting Policies**

(a)

Principles of Accounting

These financial statements are stated in U.S. Dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America.

(b)

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management makes its best estimate of the ultimate outcome for these items based on historical trends and other information available when the financial statements are prepared. Changes in estimates are recognized in accordance with the accounting rules for the estimate, which is typically in the period when new information becomes available to management. Actual results could differ from those estimates.

(c)

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company did not have any cash equivalents for the year ended December 31, 2004.

(d)

Equipment and Depreciation

Property and equipment, stated at cost and are depreciated under the straight-line method over their estimated useful lives. Repairs and maintenance are charged to operations as incurred.

(e)

Research and Development Costs

Research and development costs are expensed as incurred.

(f)

Start-up Costs

The Company accounts for start-up costs in accordance with Statement of Position (SOP) 98-5, *Reporting on the Costs of Start-up Activities.*, where they are expensed as incurred. For income tax purposes, the Company has elected to treat its organizational costs as deferred expenses and amortize them over a period of sixty months, beginning in the first month the Company is actively in business.

(g)

Income Taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes*. Under SFAS No. 109, deferred income tax assets and liabilities are computed for differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary, to reduce deferred income tax assets to the amount expected to be realized.

(h)

Earnings (Loss) Per Share

Basic earnings (loss) per share is based on the weighted average number of common shares outstanding. Diluted earnings (loss) per share is based on the weighted average number of common shares outstanding and dilutive common stock equivalents. Basic earnings (loss) per share is computed by dividing income/loss (numerator) applicable to common stockholders by the weighted average number of common shares outstanding (denominator) for the period. All earnings (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 (loss) per share for all periods presented. Convertible securities that could potentially dilute basic earnings per share in the future, such as options and warrants, 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.

(i)

# Advertising Expenses

The Company expensed advertising costs as incurred. The Company did not incur any advertising costs during the years ended December 31, 2004 and 2003.

# (j)

# Stock-Based Compensation

The Company accounts for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. Compensation cost for stock options, if any, is measured as the excess of the quoted market price of the Company s stock at the date of grant over the amount an employee must pay to acquire the stock. SFAS No.123, *Accounting for Stock-Based Compensation*, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. The Company has elected to remain on its current method of accounting as described above, and has adopted the disclosure requirements of SFAS No. 123.

(k)

# Comprehensive Income

The Company adopted Statement of Financial Accounting Standards No. 130 (SFAS No. 130), "Reporting Comprehensive Income", which establishes standards for reporting and display of comprehensive income, its components and accumulated balances. The Company is disclosing this information on its Statements of Stockholders' Equity (Deficiency). Comprehensive income comprises equity except those resulting from investments by owners and distributions to owners.

(1)

Foreign Currency Translation

The Company maintains both U.S. Dollar and Canadian Dollar bank accounts at a financial institution in Canada. Foreign currency transactions are translated into their functional currency, which is U.S. Dollar, in the following manner:

At the transaction date, each asset, liability, revenue and expense is translated into the functional currency by the use of the exchange rate in effect at that date. At the period end, monetary assets and liabilities are translated into U.S. Dollars by using the exchange rate in effect at that date. Transaction gains and losses that arise from exchange rate fluctuations are included in the results of operations.

(m)

Intangible Assets

The Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets* as of January 1, 2002, which presumes that goodwill and certain intangible assets have indefinite useful lives. Accordingly, goodwill and certain intangibles will not be amortized but rather will be tested at least annually for impairment. SFAS No. 142 also addresses

accounting and reporting for goodwill and other intangible assets subsequent to their acquisition.

The Company did not have any goodwill or intangible assets with indefinite or definite life since its inception.

(n)

Impairment of Long-Lived Assets

Long-lived assets of the Company are reviewed for impairment when changes circumstances require as to whether their carrying value has become impaired, pursuant to guidance established in the Statement of Fianncial Accounting Standards No 144 (SFAS 144), *Accounting for the Impairment or Disposal of Long-Lived Assets*. Management considers assets to be impaired if the carrying amount of an asset exceeds the future projected cash flows from related operations (undiscounted and without interest charges). If impairment is deemed to exist, the asset will be written down to fair value, and a loss is recorded as the difference between the carrying value and the fair value. Fair values are determined based on quoted market values, discounted cash flows or internal and external appraisals, as applicable. Assets to be disposed of are carried at the lower of carrying value or estimated net realizable value.

(0)

Fair Value of Financial Instruments

Fair value of financial instruments is made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgement, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair values.

The carrying value of cash and cash equivalents and accounts payable and accrued liabilities approximate their fair value because of the short-term nature of these instruments. The Company places its cash and cash equivalents with high credit quality financial institutions.

The Company operates outside of the United States of America and is exposed to foreign currency risk due to the fluctuation between the currency in which the Company operates in and the U.S. dollar.

(p)

Accounting for Derivative Instruments and Hedging Activities

The Company adopted Statement of Financial Accounting Standards Board No. 133 (SFAS 133), *Accounting for Derivative Instruments and Hedging Activities*, which requires companies to recognize all derivatives contracts as either assets or liabilities in the balance sheet and to measure them at fair value. If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (i) the changes in the fair value of the hedged asset or liability that are attributable to the hedged risk or (ii) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change.

The Company has not entered into derivative contracts either to hedge existing risks or for speculative purposes. The adoption of this pronouncement does not have an impact on the Company s financial statements.

(q)

**Related Party Transactions** 

A related party is generally defined as (i) any person that holds 10% or more of the Company s securities and their immediate families, (ii) the Company s management, (iii) someone that directly or indirectly controls, is controlled by or is under common control with the Company, or (iv) anyone who can significantly influence the financial and operating decisions of the Company. A transaction is considered to be a related party transaction when there is a transfer of resources or obligations between related parties. (See Note 4).

(r)

## New Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs-an amendment of ARB No. 43, Chapter 4*, which is the result of the FASB s project to reduce differences between U.S. and international accounting standards. SFAS No. 151 requires idle facility costs, abnormal freight, handling costs, and amounts of wasted materials (spoilage) be treated as current-period costs. Under this concept, if the costs associated with the actual level of spoilage or production defects are greater than the costs associated with the range of normal spoilage or defects, the difference would be charged to current-period expense, not included in inventory costs. SFAS No. 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 will not have a material impact on the Company s financial statements.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB* No. 29, *Accounting for Nonmonetary Transactions*. SFAS No. 153 requires exchanges of productive assets to be accounted for at fair value, rather than at carryover basis, unless (1) neither the asset received nor the asset surrendered has a fair value that is determinable within reasonable limits or (2) the transactions lack commercial substance. SFAS 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of FASB No. 153 will not have a material impact on the Company s financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Accounting for Stock-Based Compensation". SFAS 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS 123(R) requires that the fair value of such equity instruments be recognized as expense in the historical financial statements as services are performed. Prior to SFAS 123(R), only certain pro-forma disclosures of fair value were required. SFAS 123(R) shall be effective for the Company as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. The adoption of FASB No. 123(R), will not have a material impact on the Company s financial statements.

## 3.

## Equipment

	2004
	\$
Computer equipment	3,471
Furniture and fixtures	1,089
	4,560
Less: Accumulated depreciation	(3,732)

\$

828

Depreciation expense charged to operations during 2004 was \$261 (2003 \$583).

4.

# **Related Party Transactions**

(a)

Management fees

During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

(b)

Notes Payable

At a Board of Directors meeting held on May 28, 2003, the Company s Board of Directors agreed to accept a loan of up to \$750,000 from a director and major stockholder of the Company. Proceeds from the loan, which will be drawn down on a as needed basis , will be used to fund the Company s research and development commitments, legal and audit fees, investor and public relations costs and other ongoing working capital requirements.

Total unsecured promissory notes issued in 2003 of \$725,000 bearing interest at rates ranging from 7.00% to 7.25% were repaid in 2004 including accrued interest of \$51,500.

On August 27, 2004, the Company drew down \$300,000 from the loan commitment and issued an unsecured promissory note bearing an interest rate of 7.50%, due on August 27, 2005.

Accrued interest as at December 31, 2004 of \$7,187 is included in accounts payable related parties.

In December 2004, the same director and major stockholder of the Company paid \$700,000 in investor relation fees on behalf of the Company. For reimbursement, the Company issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

(c)

Amounts payable to related parties

Included in accounts payable related parties is \$17,272 (2003 - \$nil) payable to various stockholders for expenses incurred on behalf of the Company, of which \$12,595 is payable to the same director and majority shareholder in note 4b.

(d)

Rent Expenses

The Company's office is located at Suite 216, 1628 West 1st Avenue, Vancouver, British Columbia, Canada. These premises are owned by a private corporation of the same director and officer of the Company in note 4b. At present, the Company pays no rent. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

(e)

Warrants

All 2,700,000 warrants outstanding as at December 31, 2004 (2003 4,700,000) (see Note 7), are held by family members of the same director and majority stockholder in note 4b.

5.

## **Cooperative Agreement**

On November 1, 2002, the Company entered into a Cooperative Research and Development Agreement (the Agreement) with the United States Department of Agriculture's Agricultural Research Service (ARS), and committed a total payment of \$292,727 to ARS over two year period ending February 19, 2005.

On May 24, 2004, the Agreement was extended to September 30, 2007 and required total payments to ARS was amended to \$807,828 with a revised schedule of repayment as follows:

\$65,422.80 on or before 8/1/04 (paid in 2004);

\$65,422.80 on or before 11/1/04 (included in accounts payable);

\$65,422.80 on or before 2/1/05;

\$65,422.80 on or before 5/1/05;

\$65,422.80 on or before 8/1/05;

\$65,422.80 on or before 11/1/05;

\$65,422.80 on or before 2/1/06;

\$65,422.80 on or before 5/1/06;

\$65,422.80 on or before 8/1/06; and

\$65,422.80 on or before 8/1/06; and

\$65,422.80 on or before 11/1/06.

As at December 31, 2004, total payments of \$284,446 have been paid/accrued.

As amended, the Company, instead of ARS as in the original agreement, has the first option to prepare and prosecute patent or Plant Variety Protection Certificate applications, foreign and domestic, on subject invention owned or co-owned by the U.S Government, subject to certain conditions.

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. The 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.

## 6.

## Warrants

In November 2003, 7,300,000 of these warrants were exercised into common share for total proceeds of \$182,500.

In December 2004, 2,000,000 warrants were exercised into common share for total proceeds of \$50,000.

Share purchase warrants outstanding as at December 31, 2004:

Number of Warrants	Exercise Price	Expiry Date
2,700,000	<u>\$0.025</u>	March 22, 2005

Each warrant entitles the holder to acquire one common share of the Company.

7.

# **Stock Option Plan**

On July 12, 2001, the shareholders of Hepalife Technologies, Inc. approved the Company s 2001 Stock Option Plan which has 40,000,000 shares reserved for issuance thereunder, all of which were registered under Form S8 on May 8, 2003. The objective of this plan is to attract and retain the best personnel, providing for additional performance incentives, and promoting the success of the Company by providing individuals the opportunity to acquire common stock.

The Company did not grant any stock options in 2004.

On December 18, 2002, the Company s Board of Directors agreed to grant 10,000,000 Non-Statutory Stock Options out of the 40,000,000 common shares available for issuance under the Company s 2001 Stock Option Plan at \$0.07 per share being the market price at the time of the grant. The terms and conditions, such as expiration dates and vesting periods are defined in the individual stock option agreements finalized on February 10, 2003. The options are exercisable in three (3) equal installments of thirty-three and one-third percent (33 1/3%), the first installment being exercisable immediately, with an additional of thirty-three and one-third percent (33 1/3%) of the shares becoming exercisable on each of the two (2) successive anniversary dates. The options expire on February 10, 2013.

On February 12, 2003, the Board of Directors authorized the Company to grant 75,000 options to purchase common stock to a director at \$0.38 per share, being the approximate fair value at the date of grant and expiring ten (10) years from the grant date. The options become exercisable in two equal installments of fifty percent (50%), with the first installment becoming exercisable immediately and the balance becoming exercisable in 180 days from issuance. On September 22, 2003, 37,500 of these options were cancelled due to the resignation of the director from the Board of Directors.

On August 27, 2003, the Board of Directors authorized the Company to grant 3,000,000 options to purchase common stock to directors and employees of the Company at \$2.11 per share. The option price was based on the closing price of the Company s common shares on August 27, 2003. The options become exercisable in two equal installments of fifty percent (50%), with the first installment becoming exercisable immediately and the balance becoming exercisable in 180 days from issuance.

Summary of employee stock options information for the years ended on December 31, 2004 and 2003 is as follows:

		Weighted Average
	Shares	Exercise Price
		\$
Options outstanding at December 31, 2002	-	- \$
Granted	13,075,000	0.54

		\$
Exercised	(282,500)	(1.41) \$
Cancelled	(37,500)	(0.38) \$
Options outstanding at December 31, 2003	12,755,000	0.52 \$
Exercised	(1,622,000)	(0.83) \$
Options outstanding at December 31, 2004	11,133,000	0.48

	<b>Options</b>	Outstanding and Exer	cisable	
			Weighted	
			Average	Weighted
Range of			Remaining	Average
Exercise	Number	Normalian	Contractual	Exercise
Prices	Outstanding	Number exercisable	Life (yr.)	Price
			\$	
\$0.01 - \$1.00	8,915,000	5,581,666	8.10 0.07	
			\$	
\$2.00 - \$3.00	2,218,000	2,218,000	8.70 2.11	
			\$	
	11,133,000	7,799,666	8.63 0.48	

Had compensation expense for the Company's stock-based compensation plans been determined under SFAS No. 123, based on the fair market value at the grant dates, the Company's pro-forma net loss and pro-forma net loss per share would have been reflected as follows:

	200	)4	2003
Net income (loss) as reported:	\$	(1,435,613) \$	(1,102,723)
Stock-based employee compensation			

expense as determined under the		
fair value based method	(901,242)	(5,591,425)
Pro-forma, net (loss)	\$ (2,336,855) \$	(6,694,148)
Net (loss) per share		
basic and diluted:		
As reported	\$ (0.02) \$	(0.02)
Pro-forma	\$ (0.04) \$	(0.12)

The weighted average fair value of the options granted in2003 was estimated at \$0.50 by using the Black-Scholes Option Pricing Model with the following weighted average assumptions: dividend yield of 0%, expected volatility of 81.29%, risk-free interest rates of 3.5%, and expected lives of five years.

8.

## **Income Taxes**

There is no current or deferred tax expense for the years ended December 31, 2004 and 2003 due to the Company s loss position. The benefits of timing differences have not been previously recorded. The deferred tax consequences of temporary differences in reporting items for financial statement and income tax purposes are recognized, as appropriate. Realization of the future tax benefits related to the deferred tax assets is dependent on many factors, including the Company s ability to generate taxable income. Management has considered these factors in reaching its conclusion as to the valuation allowance for financial reporting purposes and has recorded a full valuation allowance against the deferred tax asset.

The income tax effect of temporary differences comprising the deferred tax assets on the accompanying balance sheet is primarily a result of start-up expenses, which are capitalized for income tax purposes. Applying a federal statutory rate of 34% to the pretax loss results in a deferred tax benefit with a full valuation allowance recorded against the benefit as follows at December 31:

	200	4		2003
NOL carryforwards	\$ 194,000	\$	57,000	
Start-up costs	1,138,000		788,000	
Organizational costs	1,020		1,020	
	1,333,020		846,020	
Valuation allowance	(1,333,020)		(846,020)	
Net deferred tax assets	\$ -	\$	-	

The Company has available net operating loss carryforwards of approximately \$570,000 (2003 \$169,000) for tax purposes to offset future taxable income which expire commencing 2008 to 2024. Additionally, the estimated effect of the charge-off of start-up expenses in 2004 is a reduction in estimated income taxes of approximately \$1,035,000 (2003 \$1,026,000), assuming normal operations have commenced.

9.

## **Subsequent Events**

On January 10, 2005, the Company extended an Investor and media relations agreement with Thornhill Advisors for another 12 months ending December 31, 2005, with monthly payments of CDN\$7,000 (US\$5,385).

# ITEM 8: CHANGE IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

We have had no disagreements with our certified public accountants with respect to accounting practices, procedures or financial disclosure.

## **ITEM 8a: CONTROLS AND PROCEDURES**

Evaluation of Disclosure Controls and Procedures

It is the Chief Executive Officer s and the Principal Financial Officer s responsibility to ensure that we maintain disclosure controls and procedures designed to provide reasonable assurance that material information, both financial and non-financial, and other information required under the securities laws to be disclosed is identified and communicated to senior management on a timely basis. Our disclosure controls and procedures include periodic management meetings to ensure communication of reportable events, receipt of ongoing advice from legal council and outside auditors on new legislation and updating, if required, the Company s disclosure controls and procedures.

## Changes in Internal Controls

During the fourth quarter of fiscal 2004, the management of the Company, including the Chief Executive Officer and the Principal Financial Officer, evaluated the Company s disclosure controls and procedures. Under rules promulgated by the SEC, disclosure controls and procedures are defined as those "controls or other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission s rules and forms." There have been no significant changes in internal controls, or in factors that could

significantly affect internal controls, subsequent to the date that management, including the Chief Executive Officer and the Principal Financial Officer, completed their evaluation.

# ITEM 9: DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Set forth below is certain information regarding each of the directors and officers of the Company:

ARIAN SOHEILI, (Age 38). CEO, President, Director. Mr. Soheili earned a Bachelor s degree in Business Administration from Simon Fraser University in 1993 and brings over 20 years of industry and public practice experience with Grant Thornton, Deloitte and Touche, and others. Since 1999, Mr. Soheili has been the Managing Director at Cantatus Systems Group, Inc., a firm that specializes in enterprise solutions, technology infrastructure and systems integration services. Mr. Soheili joined the Company as a Director and its President and Chief Executive Officer on September 22, 2003.

JASVIR S. KHELEH, (Age 31). Director. Mr. Jasvir S. Kheleh received his Diploma in Financial Management majoring in Finance from the British Columbia Institute of Technology (BCIT) in June 1995. From September 1995 to May 1996, Mr. Kheleh was employed by Canada Trust, a subsidiary of the Toronto-Dominion Bank s, TD Bank Financial Group. Initially chartered in 1855, TD is headquartered in Toronto, Canada with more than 51,000 employees and \$300 billion (cdn) in assets. Since June 1996, Mr. Kheleh has been with the nation s largest credit union institution, Vancity (Vancouver City Savings Credit Union) as a Financial Services Manager. Mr. Kheleh joined the Company as a Director on November 19, 2003.

HARMEL S. RAYAT, (Age 43). Secretary, Treasurer, Director. Mr. Rayat has been in the venture capital industry since 1981. Between January 1993 and April 2001, Mr. Rayat served as the president of Hartford Capital Corporation, a company that provides financial consulting services to emerging growth corporations. From April 2001 through January 2002, Mr. Rayat acted as an independent consultant advising small corporations. Since January 2002, Mr. Rayat has been president of Montgomery Asset Management Corporation, a privately held firm providing financial consulting services to emerging growth corporations. Mr. Rayat is also a Director of Entheos Technologies, Inc., Enterprise Technologies Corporation and eDeal.net, Inc. Mr. Rayat has served as a Director of the Company since December 4, 2000.

On October 23, 2003, Mr. Harmel S. Rayat, EquityAlert.com, Inc., Innotech Corporation and Mr. Bhupinder S. Mann, a former part-time employee of the Company, collectively the respondents, consented to a cease-and-desist order pursuant to Section 8A of the Securities Act of 1933. Without admitting or denying the findings of the Securities and Exchange Commission related to the public relation and stock advertising activities of EquityAlert.com, Inc. and Innotech Corporation, the respondents agreed to cease and desist from committing or causing any violations and any

future violations of Section 5(a) and 5(c) of the Securities Act of 1933. EquityAlert.com, Inc. and Innotech Corporation agreed to pay disgorgement and prejudgment interest of \$31,555.14. On August 8, 2000, Mr. Harmel S. Rayat and EquityAlert.com, Inc., without admitting or denying the allegations of the Securities and Exchange Commission that EquityAlert.com, Inc did not disclose certain compensation received by it in connection with stock advertisements and promotions, consented to the entry of a permanent injunction enjoining them from violating Section 17(b) of the Securities Act of 1933; in addition, each agreed to pay a civil penalty of \$20,000.

## Compliance With Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's directors, officers and persons who own more than 10 percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("the Commission"). Directors, officers and greater than 10 percent beneficial owners are required by applicable regulations to furnish the Company with copies of all forms they file with the Commission pursuant to Section 16(a). Based solely upon a review of the copies of the forms furnished to the Company, the Company believes that during fiscal 2004 the Section 16(a) filing requirements applicable to its directors and executive officers were satisfied.

## **ITEM 10: EXECUTIVE COMPENSATION**

## Remuneration and Executive Compensation

The following table shows, for the three-year period ended December 31, 2004, the cash compensation paid by the Company, as well as certain other compensation paid for such year, to the Company's Chief Executive Officer and the Company's other most highly compensated executive officers. Except as set forth on the following table, no executive officer of the Company had a total annual salary and bonus for 2004 that exceeded \$100,000.

Summary Compensation Table

Securities

Underlying

Name and

Options

	0	0		
All Other				
Principal Position	Year	<u>Salary</u>		
Bonus Other				
Granted				
Compensation				
Harmel S. Rayat (1)				
2004				
\$0				
\$0				
\$3,500				
0				
\$0				
Secretary, Treasurer,				
2003				
\$27,000				
\$0				
\$0				
1,500,000				
\$0				
Director				
2002				
\$144,000				
\$0				
\$0				

5,500,000	
\$0	
Arian Soheili	
2004	
\$0	
\$0	
\$2,500	
0	
\$0	
CEO, President,	
2003	
\$0	
\$0	
\$1,150	
0	
\$0	
Director	
2002	
\$0	
\$0	
\$0	

\$0	
Jasvir Kheleh,	
2004	
\$0	
\$0	
\$3,500	
0	
\$0	
Director	
2003	
\$0	
\$0	
\$350	
0	
\$0	
2002	
\$0	
\$0	
\$0	
0	
\$0	

(1) During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable-related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

## Stock Option Grants in Last Fiscal Year

Shown below is further information regarding employee stock options awarded during 2004 to the named officers and directors:

Number of

% of Total

Securities

**Options Granted** 

Underlying

to Employees

Exercise

Expiration

### <u>Name</u>

**Options** 

## <u>in 2004</u>

Price (\$/sh)

<u>Date</u>

0	
0	
n/a	
n/a	
Harmel Rayat	
0	
0	
n/a	
n/a	
Jasvir Kheleh	
0	
0	
n/a	
n/a	

## Aggregated Option Exercises During Last Fiscal Year and Year End Option Values

The following table shows certain information about unexercised options at year-end with respect to the named officers and directors:

Common Shares Underlying Unexercised

Value of Unexercised In-the-money

Options on December 31, 2004

Options on December 31, 2004

<u>Name</u>

Exercisable

# Changes in Control

There are no understandings or agreements, aside from the transaction completed and described under Certain Relationships and Related Transactions, known by management at this time which would result in a change in control of the Company. If such transactions are consummated, of which there can be no assurance, the Company may issue a significant number of shares of capital stock which could result in a change in control and/or a change in the Company s current management.

## ITEM 11: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of March 29, 2005, the beneficial ownership of the Company's Common Stock by each director and executive officer of the Company and each person known by the Company to beneficially own more than 5% of the Company's Common Stock outstanding as of such date and the executive officers and directors of the Company as a group.

Number of Shares

Person or Group

of Common Stock

Percent

Harmel S. Rayat (1)

46,463,056

68%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Harmel S. Rayat (2)

7,000,000

11%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Arian Soheili

0

0%

# 216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Jasvir Kheleh

0

0%

216-1628 West First Avenue

Vancouver, B.C. V6J 1G1 Canada

Directors and Executive Officers

53,463,056

79%

as a group (3 persons)

(1) Includes 3,203,194 shares held by Tajinder Chohan, Mr. Harmel S. Rayat's wife. Additionally, other members of Mr. Rayat's family hold shares and share purchase warrants. Mr. Rayat disclaims beneficial ownership of the shares and share purchase warrants beneficially owned by his wife and other family members.

(2) Includes 5,500,000 stock options granted on February 10, 2003 and 1,500,000 stock options granted on August 27, 2003, which may be acquired pursuant to options granted and exercisable under the Company's stock option plans.

# **ITEM 12: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

(a) Management fees

During 2004, the Company incurred \$9,500 (2003 \$28,500) in management fees to directors of the Company. Included in accounts payable related parties at December 31, 2004 is management and consulting fees of \$1,600 incurred in 2004 and \$27,000 incurred in previous years.

(b) Notes Payable

At a Board of Directors meeting held on May 28, 2003, the Company s Board of Directors agreed to accept a loan of up to \$750,000 from a director and major stockholder of the Company. Proceeds from the loan, which will be drawn down on an as needed basis , will be used to fund the Company s research and development commitments, legal and audit fees, ongoing investor and public relations costs and other working capital requirements.

Total unsecured promissory notes issued in 2003 of \$725,000 bearing interest at rates ranging from 7.00% to 7.25% were repaid in 2004 including accrued interest of \$51,500.

On August 27, 2004, the Company drew down \$300,000 from the loan commitment and issued an unsecured promissory note bearing an interest rate of 7.50%, due on August 27, 2005.

Accrued interest as at December 31, 2004 of \$7,187 is included in accounts payable related parties.

In December 2004, the same director and major stockholder of the Company paid \$700,000 in investor relation fees on behalf of the Company. For reimbursement, the Company issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

(c) Amounts payable to related parties

Included in accounts payable related parties is \$17,272 (2003 - \$nil) payable to various stockholders for expenses incurred on behalf of the Company, of which \$12,595 is payable to the same director and majority shareholder in note b above.

(d) Rent Expenses

The Company's office is located at Suite 216, 1628 West 1st Avenue, Vancouver, British Columbia, Canada. These premises are owned by a private corporation of the same director and officer of the Company in note b above. At present, the Company pays no rent. The fair value of the rent has not been included in the financial statements because the amount is immaterial.

(e) Warrants

All 2,700,000 warrants outstanding as at December 31, 2004 (2003 4,700,000) (see Note 7), are held by unaffiliated family members of the same director and majority stockholder in note b above.

# ITEM 13: EXHIBITS AND REPORTS ON FORM 8-K

(a) The following exhibits are filed as part of this Annual Report:

### 31.1

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

## 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) During the Company s fourth quarter, the following reports were filed on Form 8-K

<u>December 8, 2004:</u> HepaLife Technologies, Inc. issued a news release to announce the addition of Dr. Jorge Alberto Ortiz to the Company s Scientific Advisory Board.

<u>December 15, 2004</u>: HepaLife Technologies, Inc. issued a news release to announce its expectations of increased drug induced liver injuries and adverse drug reactions due to a dramatic rise in prescription drug usage amongst Americans, with almost half of the population now taking at least one prescription drug and one person in every six taking three or more (Centers for Disease Control and Prevention, December 2, 2004).

# ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The firm of Moore Stephens Ellis Foster Ltd. currently serves as the Company's independent accountants. The Board of Directors of the Company, in its discretion, may direct the appointment of different public accountants at any time during the year, if the Board believes that a change would be in the best interests of the stockholders. The Board of Directors has considered the audit fees, audit-related fees, tax fees and other fees paid to the Company's accountants, as disclosed below, and had determined that the payment of such fees is compatible with maintaining the independence of the accountants.

Audit Fees: The aggregate fees, including expenses, billed by the Company's principal accountant in connection with the audit of our consolidated financial statements for the most recent fiscal year and for the review of our financial information included in our Annual Report on Form 10-KSB; and our quarterly reports on Form 10-QSB during the fiscal years ending December 31, 2004 and December 31, 2003 were \$7,686 and \$9,167 respectively.

Tax fees: The aggregate fees billed to the Company for tax compliance, tax advice and tax planning by the Company s principal accountant for fiscal 2004 and 2003 were \$0.

All Other Fees: The aggregate fees, including expenses, billed for all other services rendered to the Company by its principal accountant during year 2004 and 2003 were \$0.

The Company does not currently have an audit committee.

## SIGNATURES

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 31st day of March, 2005.

HepaLife Technologies, Inc.

/s/ Arian Soheili

Arian Soheili

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** 

<u>Title</u>

Date

### /s/ Arian Soheili

Director, President,

March 31, 2005

Arian Soheili

Chief Executive Officer

/s/ Jasvir Kheleh

Director

March 31, 2005

Jasvir Kheleh

/s/ Harmel Rayat

Director, Secretary/Treasurer,

March 31, 2005

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 annual report on Form 10-KSB 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: March 31, 2005

By: <u>/s/ Arian Soheili</u> Arian Soheili President and Chief Executive Officer

## 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 annual report on Form 10-KSB 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: March 31, 2005

By: <u>/s/ Harmel Rayat</u> Harmel Rayat Principal Financial Officer

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 Annual Report of HepaLife Technologies, Inc. (the Company ) on the Form 10-KSB for the period ending December 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: March 31, 2005

By:

<u>/s/ Arian Soheili</u> 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 Annual Report of HepaLife Technologies, Inc. (the Company ) on the Form 10-KSB for the period ending December 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:

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: March 31, 2005

By:

<u>/s/ Harmel Rayat</u> 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.