

HEPALIFE TECHNOLOGIES INC  
Form 10KSB/A  
February 08, 2006

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-KSB/A**

**Amendment No. 2**

**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)**

**58-2349413**

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

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

(Address of principal executive offices)

**(800) 518-4879**

(Registrant's telephone number, including area code)

**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 January 23, 2006: \$32,847,294. Number of shares of Common Stock, \$0.001 par value, outstanding as of January 23, 2006: 70,439,183.

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



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## PART I

### ITEM 1. DESCRIPTION OF BUSINESS.

#### Forward-Looking Statements

Except for the historical information presented in this document, the matters discussed in this Form 10-KSB/A for the fiscal year ending December 31, 2004, this report contains forward-looking statements. Such forward-looking statements include statements regarding, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) our future financing plans, and (e) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words *may*, *will*, *should*, *expect*, *anticipate*, *estimate*, *intend*, or *project* or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under *Management's Discussion and Analysis or Plan of Operation*, *Description of Business*, *Description of Property*, as well as in this report generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under *Risk Factors* and matters described in this report generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur.

#### The Company

We are a Florida corporation, formed in 1997 under the name Zeta Corporation. We changed our name on April 17, 2003, to more accurately reflect our business. We are authorized to issue up to 300,000,000 shares of common stock (of which 70,439,183 were issued and outstanding on January 20, 2006) and 1,000,000 shares of preferred stock (none of which has been issued).

#### Description of Business

We are an early stage, research and development based 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. We currently do not directly conduct any of our research and development activities. Rather, once a technology has been identified, we fund the research and development activities relating to the technology with the intention of ultimately, if warranted, licensing, commercializing and



marketing the subject technology. We do not have, and may never develop, any commercialized products. We have not generated any revenue from our current operations and do not expect to do so for the foreseeable future.

Our sponsored research is being conducted pursuant to a Cooperative Research and Development Agreement ( CRADA ) with the United States Department of Agriculture (the USDA ) Agricultural Research Service. Currently, we are concentrating our sponsored research and development efforts on developing an artificial liver device and in-vitro toxicology and pre-clinical drug testing platforms.

HepaLife s ongoing sponsored 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.

### **Artificial Liver Device**

We are working towards optimizing the hepatic (liver) functionality of a porcine cell line, and subclones thereof, which we refer to as the PICM-19 Cell Line. The PICM-19 Cell Line was developed and patented by USDA s Agricultural Research Service scientists. U.S. Patent #5,532,156 (Hepatocyte Cell Line Derived from the Epiblast of Pig Blastocysts ) was issued on July 2, 1996, and U.S. Patent #5,866,420 (Artificial liver device) was issued on February 2, 1999.

The hepatic characteristics of the PICM-19 Cell Line have been demonstrated to have potential application in the production of an artificial liver device, which application was also developed and patented by USDA's Agricultural Research Service scientists for potential use by human patients with liver failure.

### **In-Vitro Toxicology Testing**

The PICM-19 Cell Line, grown in-vitro, can synthesize liver specific proteins such as albumin and transferrin, and display enhanced liver-specific functions, such as ureagenesis (conversion of ammonia to urea) and cytochrome P450 (a family of over 60 enzymes the body uses to break down toxins and make blood) activity. The P-450 enzyme systems are key components in the overall hepatic detoxification pathway of drugs and other xenobiotics (toxic foreign chemicals which can be both man-made and natural chemicals, such as pesticides and pollutants). Likewise, ureagenesis is another important hepatic function since urea production is required for the detoxification of ammonia derived from the catabolism (breakdown of complex organic molecules into simpler components) of a number of nitrogen containing compounds. As a result, we believe the PICM-19 Cell Line could be an important element in developing in-vitro toxicological and pre-clinical drug testing platforms that could more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

### **Our Strategy**

Our sponsored research is focused on optimizing the hepatic functionality of the PICM-19 Cell Line, and subclones thereof, for use in the production of an artificial liver device for human patients with liver failure. The successful adaptation and application of an optimized PICM-19 Cell Line, along with the development of an artificial liver device, would allow us to target the estimated 25 million Americans that are or have been afflicted with liver and biliary disease.

Based upon our assessment of the information and data obtained in connection with our decision to enter into the CRADA and subsequently obtained from our ongoing sponsored research efforts, we anticipate that an artificial liver device, once approved for use by appropriate regulatory agencies, could be used either as a temporary artificial liver for patients awaiting a liver transplant, thus lengthening the time they have available while an organ donor is located, or it could provide support for post-transplantation patients until a grafted liver functions adequately to sustain the patient. Additionally, an artificial liver device could also be used as support for patients with chronic liver disease, thus allowing their own liver time to heal and regenerate, as well as providing immediate temporary support for those patients suffering from acute liver failure, as is the case with drug overdoses.

Assuming we succeed in our sponsored research and development efforts into the optimization of the PICM-19 Cell Line, the development of an artificial liver device incorporating the optimized PICM-19 Cell Line and in obtaining a license pursuant to our CRADA, we will explore a number of commercial opportunities, including, but not limited to: the outright sale of our technology, joint venture partnerships with health care companies, or our direct marketing and selling of the products, if any, derived from the sponsored research and development efforts.

We are also targeting the toxicological and pre-clinical drug testing markets through the development of in-vitro toxicological and pre-clinical drug testing platforms using the PICM-19 Cell Line. Resulting in part from the limitations of current testing methodology, safety problems relating to drug usage are often discovered only during clinical trials, and unfortunately, sometimes after marketing. 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 FDA, generally resulting in substantial costs to the manufacturer.

Our commercial success will depend on our ability and the ability of our sublicensees, if any, to compete effectively in product development areas such as, but not limited to, safety, efficacy, ease of use, patient or customer compliance, price, marketing and distribution. There can be no assurance that competitors will not succeed in developing products that are more effective than any that may ultimately be derived from our sponsored research and development efforts or that would render any such product obsolete and non-competitive.

## Our Intended Markets

Assuming the results from our sponsored ongoing research and development efforts prove successful, and subject to our receiving regulatory approvals, we, based upon our discussions with representatives of the USDA, the USDA's Agriculture Research Service scientists and the related input from our advisory board scientists, believe that we will have the potential to address two important market segments:

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the liver disease market through the development of an artificial liver device; and

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the toxicological and pre-clinical drug testing market through the development of in-vitro toxicological and pre-clinical drug testing platforms that may more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

Our ability to achieve profitability is dependent in part on ultimately obtaining regulatory approvals for products, if any, which are derived from our sponsored research and development efforts, and then entering into agreements for the commercialization of any such products. There can be no assurance that such regulatory approvals will be obtained or such agreements will be entered into. The failure to obtain any such necessary regulatory approvals or to enter into any such necessary agreements could delay or prevent us from achieving profitability and would have a material adverse effect on the business, financial position and results of our operations. Further, there can be no assurance that our operations will become profitable even if products, if any, which are derived from our sponsored research and development efforts, are commercialized.

If FDA and other approvals are ultimately obtained with respect to any product submitted by us in the future for approval, we expect to market and sell any such product through distribution, co-marketing, co-promotion or sublicensing arrangements with third parties. We have no experience in sales, marketing or distribution of biotechnology products and our current management and staff is not trained in these areas.

To date, we have no such agreements. To the extent that we enter into distribution, co-marketing, co-promotion or sublicensing arrangements for the marketing and sale of any such products, any revenues received by us will be dependent on the efforts of third parties. If any of such parties were to breach or terminate their agreement with us or otherwise fail to conduct marketing activities successfully, and in a timely manner, the commercialization of products, if any, derived from our research and development efforts would be delayed or terminated.

*Liver Disease and the Need for an Artificial Liver Device*

There is widespread agreement among the medical community that a rescue or bridging device that could supply short-term liver support to patients suffering acute liver failure due to disease or chemical toxicity is a necessary tool for viable treatment options. The need for such a device is increasing world wide. As mentioned above, it is believed that the major impediment to developing such a device is the availability of an optimal cell or cell line that could provide sustained liver function. Our overall goal is to provide a complete system to hospital centers that will be ready to use when a patient is diagnosed with insufficient liver function. The core of our system will be a bioreactor or cell culture device that could house and maintain a healthy population of liver cells from the PICM 19 Cell Line, or subclones thereof, with high metabolic activity in sufficient quantity to provide adequate hepatic detoxification functions. To ensure biological integrity and to maintain the highest quality of the bioreactor's liver cells, we would supply fully functional bioreactors that would incorporate, or be compatible with, presently used dialysis devices so that the patient's plasma could be effectively detoxified by transit through the bioreactor before being returned to the patient.

The National Institutes of Health ( NIH ) has estimated that one quarter of Americans will suffer from a liver or biliary disease at some point in their lifetime. These findings have been corroborated by other health organizations which have indicated that an estimated 25 million Americans are or have been afflicted with liver or biliary diseases. According to the National Institutes of Health (NIH-NIDDK), it is estimated that expenses of approximately \$10 billion annually are incurred in the treatment of liver disease and associated conditions. Based on published data, we believe that over \$1.5 billion of this market represents the most acute patient population in urgent need of an artificial liver device. We are not aware of any negative reports, data or findings regarding the potential benefits of an effective artificial liver device.

Among those in greatest need, are the 6,169 Americans who underwent liver transplantation procedures in 2004 at a cost of \$250,000 per surgery, notwithstanding pre- and post-operative expenses (American Liver Foundation); this market segment alone amounts to \$1.54 billion per year.

In addition, the United Network for Organ Sharing estimates that 17,440 persons were awaiting liver transplants as of September 2005. If this waiting list patient population were able to undergo liver transplantation, these patients would account for an additional \$4.36 billion in additional to medical care costs.

Causes of liver disease and related conditions include:

#### Alcohol Abuse

Of the nearly 14 million estimated Americans that either abuse alcohol or are alcoholics, approximately 10 to 20% are expected to develop cirrhosis of the liver, one of the leading causes of death among young and middle-age adults in the United States. Individuals with cirrhosis are particularly prone to developing fatal bacterial infections and cancer of the liver.

#### Drug Induced Conditions

Adverse drug reactions are an increasingly important clinical problem in medicine today and rank among the ten most common causes of death. 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.

#### Hepatitis

According to publicly available statistical information, approximately 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.

Of the estimated 4.5 million Americans infected with hepatitis C, for which at this time there is no known cure, an estimated 70-80% will develop chronic liver disease and of these, approximately 20% will die. The annual health care costs for the affected U.S. population with chronic hepatitis C alone has been estimated to be as high as \$9 billion,

compared to annual cost of \$360 million for hepatitis B sufferers.

Other Medical Conditions

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.

For people with severe liver failure, orthotopic liver transplantation is the most prescribed and effective treatment therapy available today. At present, there are upwards of 17,000 adults and children medically approved and waiting for liver transplants in the United States. 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 waiting period.

For persons who receive liver transplants, it is estimated that approximately 30% will die within 5 years of transplantation. The balance will require immunosuppressive drugs, rendering them susceptible to life threatening infections such as kidney failure and increased risk of cancer.

Because of 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, we believe that a market opportunity for an artificial liver device able to remove toxins and improve immediate and long-term survival exists at this time.

*The Need for Improved In Vitro Toxicology Testing*

In 2003 alone, the inability to accurately predict toxicity early in drug development cost the pharmaceutical industry a record \$8 billion. In particular, 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 FDA. In fact, about one third of all potential drugs fail pre-clinical or clinical trials due to the toxic nature of the compounds being tested, accounting for an estimated \$70 million (20%) of total research and development costs per drug.

The pharmaceutical industry has sought ways to identify liver toxicity at earlier stages of drug development, preferably without animal testing, often considered expensive and inaccurate, and socially contentious. As a result, cell-based testing has emerged as a low-cost, early toxicity detection tool in ADME-Tox research.

We believe that our in-vitro toxicology testing technology can reasonably target the broad in-vitro toxicology testing market, a segment expected to reach \$1.96 billion by 2007 at an average annual growth rate of 12.1% (Business Communications Company, Inc; B-110R; The Market for in Vitro Toxicology Testing; Samuel Brauer PhD; June 2003).

**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.*

## **RISKS ASSOCIATED WITH OUR BUSINESS**

### *We Have Experienced Significant Losses And Expect Losses To Continue For The Foreseeable Future.*

We have yet to establish any history of profitable operations. We have incurred annual operating losses of \$1,435,613 and \$1,102,723, respectively, during the past two fiscal years of operation. As a result, at December 31, 2004, we had an accumulated deficit of \$3,747,771. We had no revenues during the last five fiscal years and we do not expect to generate revenues from our operations for the foreseeable future. Our profitability will require the successful completion of our sponsored research, development efforts and the subsequent commercialization of our products, if any, derived from our sponsored research and development activities regarding our artificial liver device and in-vitro toxicology testing methodologies. No assurances can be given when this will occur or that we will ever be profitable.

To date most of our operating losses have been related to expenditures related to our advertising and investor relations program rather than to our sponsored research and development program.

Since inception through December 31, 2004, we have expended a total of \$2,096,419 in connection with our advertising and investor relations representing approximately 56% of our total expenses for the period as compared to total expenditures of \$284,446 or approximately 8% of our total expenses for the period. Subsequently in 2005 (through September 30), we expended an additional \$705,330 on our advertising and investor relations program and only \$196,269 on our research and development activities. From inception through September 30, 2005 expenditures for our advertising and investor relations expenditures aggregated \$2,801,749 or approximately 56% of total expenditures as compared to total research and development expenses during the same period of \$480,715 or approximately 10% of total expenditures. If we continue to expend funds in such a disproportionate manner we may not have sufficient capital for the completion of our obligations under the CRADA or for the acquisition and development of new technologies. This would have an adverse affect on our operations and potential profitability, in which case we may need to substantially curtail or cease our research and development activities.

We Currently Do Not Have, And May Never Develop, Any Commercialized Products.

We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources over the last three years in identification, research and development of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease. The technologies, which are the subject of our ongoing sponsored research programs, will require additional development, clinical evaluation, regulatory approval, significant marketing efforts and substantial additional investment (beyond the \$807,828 to which we have committed under the terms of our CRADA) before they can provide us with any revenue. We cannot currently estimate with any accuracy the amount of these funds because it may vary significantly depending on the results of our current sponsored research and development activities, product testing, costs of acquiring licenses, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory process, manufacturing, marketing and other costs associated with the commercialization of products following receipt of approval from regulatory bodies and other factors.

Our efforts may not lead to commercially successful products for a number of reasons, including:

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we may not be able to obtain regulatory approvals or the approved indication may be narrower than we seek;

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our technologies or products, if any, derived from our research and development efforts may not prove to be safe and effective in clinical trials;

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physicians may not receive any reimbursement from third-party payors, or the level of reimbursement may be insufficient to support widespread adoption of any products derived from our research and development efforts;

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any products that may be approved may not be accepted in the marketplace by physicians or patients;

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we may not have adequate financial or other resources to complete the development and commercialization of products derived from our research and development efforts;

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we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and

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rapid technological change may make our technologies and products derived from those technologies obsolete.

*We Will Require Additional Financing To Sustain Our Operations And Without It We Will Not Be Able To Continue Operations.*

Our independent auditors have added an explanatory paragraph to their audit opinion issued in connection with the financial statements for the years ended December 31, 2004 and 2003, relative to our ability to continue as a going concern. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

At December 31, 2004, we had a working capital deficit of \$539,779. We have an operating cash flow deficit of \$1,364,209 in 2004 and \$1,022,501 in 2003. Although we believe that we have sufficient financial resources and commitments to sustain our current level of research and development activities through the end of February 28,

2006, any expansion, acceleration or continuation (beyond February 28, 2006) of such activities will require additional capital which may not be available to us, if at all, on terms and conditions that we find acceptable.

On January 20, 2006 we entered into a new common stock purchase agreement with Fusion Capital Fund II, LLC pursuant to which Fusion Capital has agreed, so long as no event of default (as described below) exists, to purchase on each trading day \$25,000 of our common stock up to an aggregate of \$15.0 million over a 30 month period subject to earlier termination at our discretion. In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$0.50.

We shall not commence any sale of our common stock to Fusion Capital until a registration statement registering 11,086,351 shares, of which 10,000,000 may be sold to Fusion Capital pursuant to the common stock purchase agreement, has been declared effective by the U.S. Securities and Exchange commission. The extent we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, including other debt and equity financings.

*We May Not Be Able To Repay Loans We Have Received From Harmel S. Rayat, Our President, Director And Majority Stockholder, To Fund Our Operation.*

We have borrowed an aggregate of \$1,150,000 from Harmel S. Rayat, our president, director and majority stockholder, pursuant to his \$1,600,000 loan commitment to us. The loans are due upon the receipt of the written demand from Mr. Rayat. The loans bear interest at the rate of 8.50% per annum. We do not currently have sufficient capital on hand to repay these loans. We may prepay these loans, at any time, without penalty. We expect to repay these amounts from the proceeds, if any, we receive under the common stock purchase agreement with Fusion Capital. There is no assurance that we will be able to repay all or a part of these loans or obtain any additional loans from Mr. Rayat in the event we do not receive the proceeds from Fusion Capital.

*The Success Of Our Sponsored Research And Development Program Is Uncertain And We Expect To Be Engaged In Research And Development Efforts For A Considerable Period Of Time Before We Will Be In A Position, If Ever, To Develop And Commercialize Products Derived From Our Sponsored Research Program.*

We expect to continue our current sponsored research and development program through at least 2007. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual costs may exceed the amounts (\$807,828) we have budgeted and actual time may exceed our expectations. If our research and development requires more funding or time than we anticipate, then we may have to reduce technological development efforts or seek additional financing. There can be no assurance that we

will be able to secure any necessary additional financing or that such financing would be available to us on favorable terms. Additional financings could result in substantial dilution to existing stockholders. Even if we are able to fully fund our research and development program, there is no assurance that, even upon successful completion of our program, we will ever be able to commercialize products if any, derived from our research efforts or that we will be able to generate any revenues from operations.

*Our Sponsored Research and Development Program Is In The Preliminary Development Stage And The Results We Attain May Not Prove To Be Adequate For Purposes of Developing and Commercializing Any Products Or Otherwise To Support A Profitable Business Venture.*

Our sponsored research and development program is in the preliminary development stage. Our program is targeting specifically in-vitro toxicology and drug testing platforms and the development of an artificial liver device. We will require significant further research, development, testing and regulatory approvals and significant additional investment (beyond the \$807,828 to which we have committed under the terms of our CRADA) before we will be in a position to attempt to commercialize products derived from our research and development program. We cannot currently estimate with any accuracy the amount of these funds because it may vary significantly depending on the results of our current sponsored research and development activities, product testing, costs of acquiring licenses, changes in the focus and direction of our research and development programs, competitive and technological

advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory process, manufacturing, marketing and other costs associated with commercialization of products following receipt of approval from regulatory bodies and other factors.

There can be no assurances that our early stage sponsored research will be successful. The ultimate results of our ongoing research program may demonstrate that the technologies being researched by us may be ineffective, unsafe or unlikely to receive necessary regulatory approvals, if ever. If such results are obtained, we will be unable to create marketable products or generate revenues and we may have to cease operations.

We have not submitted any products or any technologies that are the subject of, or result from, our research and development activities for regulatory approval or clearance. Even if our research is successful, the process of obtaining necessary U.S. Food and Drug Administration ( FDA ) approvals or clearances can take years and is expensive and full of uncertainties. Additionally, approved products are subject to continuing FDA requirements relating to quality control and quality assurance, maintenance of records, reporting of adverse events and product recalls, documentation, labeling and promotion of medical products. Compliance with such continued regulatory oversight may prove to be costly and may limit our ability to attain profitable operations.

*We May Not Be Granted An Exclusive License Under Our CRADA With The USDA s Agricultural Research Service.*

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We are a party to a CRADA with the USDA s Agricultural Research Service which grants us an option to negotiate an exclusive license to any invention or other intellectual property conceived or reduced to practice under the CRADA 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 materially 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 products, if any, derived from our ongoing sponsored research and development programs.

*Our CRADA With The USDA s Agricultural Research Service May Be Terminated By Either Party At Any Time By Giving Written Notice Of Not Less Than Sixty Calendar Days Prior To The Desired Termination Date.*

Our current sponsored research and development program is based entirely on our CRADA with the USDA's Agricultural Research Service. The termination date of the CRADA is September 30, 2007. However, the CRADA provides that it may be terminated unilaterally by either us or the USDA's Agricultural Research Service upon written notice of not less than sixty calendar days prior to the desired termination date. This means that the USDA's Agricultural Research Service could terminate the CRADA even if we are not in default under the terms of the Agreement. If the USDA's Agricultural Research Service were to do so, our business and future prospects would be materially adversely affected.

*Currently, We Do Not Directly Conduct Any Of Our Research And Development Activities And Therefore We Will Have Minimal Control Over Such Research.*

We rely primarily on the USDA's Agricultural Research Service to conduct, monitor and assess our sponsored research. We will have no control over the specifics of and possible direction that the research may take.

Accordingly, there can be no assurance that the USDA's Agricultural Research Service will conduct our sponsored research in a manner that will lead to the commercial development of any products.

We are also dependent upon the services of certain key scientific personnel who are not employed by us, including the principal investigators with respect to our on going research regarding both the treatment of liver disease (and related conditions), including the development of an artificial liver device, and in-vitro toxicology testing technologies. The loss of the services provided by such persons could have a materially adverse effect on us, unless

qualified replacements could be found. We have no control over whether our principal investigators or other scientific personnel will choose to remain involved with our projects. Since these individuals are not bound by contract to us nor employed by us directly, they might move on to other research or positions.

*We Are Subject To Substantial Government Regulation Which Could Materially Adversely Affect Our Business.*

We have yet to develop any products for submission for regulatory approval. If any such products are submitted for approval, they must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, harder and more costly to bring any products to market; moreover, we cannot guarantee that approval will be granted. The pre-marketing approval process can be particularly expensive, uncertain and lengthy. Many products for which FDA have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions and criminal prosecution.

Delays in, or rejection of, FDA or other government entity approval may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, slower than expected rate of patient recruitment for clinical trials, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development in the United States. In the United States more stringent FDA oversight in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk and significantly higher expenses. Even if regulatory approval for any product is granted, this approval may entail limitations on uses for which any such product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our sponsored research and development efforts for broader or different applications or to market updated products that represent extensions of any such product. In addition, we may not receive FDA approval to export any such product in the future, and countries to which products are to be exported may not approve them for import.

Any manufacturing facilities would also be subject to continual review and inspection. The FDA has stated publicly that compliance with manufacturing regulations will be scrutinized more strictly. A governmental authority may challenge our compliance with applicable federal, state and foreign regulations. In addition, any discovery of previously unknown problems with any of our sponsored research and development efforts or products derived from such research and development, or facilities may result in marketing, sales and manufacturing restrictions, being imposed, as well as possible enforcement actions.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our research and development programs and products, if any, derived from such research. It is possible that the FDA will issue additional regulations further restricting the sale of our products, if any, derived from our research and development efforts. Any change in legislation or regulations that govern the review and approval process relating



to could make it more difficult and costly to obtain approval, or to produce, market, and distribute such products, if any, derived from our research and development efforts, even if approved.

*We May Be Required To Comply With Rules Regarding Animal Testing and This May Limit the Success of Our Research and Development Program.*

Our sponsored research and development efforts involve laboratory animals. We may be adversely affected by changes in laws, regulations or accepted procedures applicable to animal testing or by social pressures that would restrict the use of animals in testing or by actions against our collaborators or us by groups or individuals opposed to such testing.

*Our Sponsored Research and Development Program Uses Cells Derived From Pigs, Which Could Prevent The FDA Or Other Health Regulatory Agencies From Approving Products, If Any, Derived From Our Research and Development Efforts.*

Because pigs carry genetic material of the porcine endogenous retrovirus ( PERV ), our use of cells derived from pigs carries a risk of transmitting viruses harmless to pigs, but deadly to humans. This may result in the FDA or other health regulatory agencies not approving products, if any, derived from our sponsored research and development efforts or subsequently banning any further use of any such products should health concerns arise after any such product was approved. At this time, it is unclear whether we will be able to obtain clinical and product liability insurance that covers the PERV risk.

*We May Be Liable For Contamination Or Other Harm Caused By Materials That We Handle, And Changes In Environmental Regulations Could Cause Us To Incur Additional Expense.*

Our sponsored research and development programs do not generally involve the handling of potentially harmful biological materials or hazardous materials, but they may occasionally do so. The USDA's Agricultural Research Service and we are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our business, financial condition and results of operations. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We may be subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

*Even If We Were To Secure Regulatory Approval In The Future For Any Product Derived From Our Sponsored Ongoing Research Efforts, We Lack Sales and Marketing Experience and Will Likely Rely On Third Parties For Such Services.*

Our ability to achieve profitability is dependent in part on ultimately obtaining regulatory approvals for products, if any, which are derived from our sponsored research and development efforts, and then entering into agreements for the commercialization of any such products. There can be no assurance that such regulatory approvals will be obtained or such agreements will be entered into. The failure to obtain any such necessary regulatory approvals or to enter into any such necessary agreements could delay or prevent us from achieving profitability and would have a material adverse effect on the business, financial position and results of our operations. Further, there can be no assurance that our operations will become profitable even if products, if any, which are derived from our sponsored research and development efforts, are commercialized.

If FDA and other approvals are ultimately obtained with respect to any product submitted by us in the future for approval, we expect to market and sell any such product through distribution, co-marketing, co-promotion or sublicensing arrangements with third parties. We have no experience in sales, marketing or distribution of biotechnology products and our current management and staff is not trained in these areas. To date, we have no such agreements. To the extent that we enter into distribution, co-marketing, co-promotion or sublicensing arrangements for the marketing and sale of any such products, any revenues received by us will be dependent on the efforts of third parties. If any of such parties were to breach or terminate their agreement with us or otherwise fail to conduct marketing activities successfully, and in a timely manner, the commercialization of products, if any, derived from our research and development efforts would be delayed or terminated.

*We May Not Be Able To Attract And Retain Qualified Personnel Either As Employees Or As Consultants; Without Such Personnel, We May Not Be Successful In Commercializing The Results Of Our Ongoing Research And Development Efforts.*

Competition for qualified employees among companies in the biotechnology industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. Our present management has no

clinical or other experience in the development of biotechnology products. Attracting desirable employees will require us to offer competitive compensation packages, including possible stock options. In order to successfully commercialize the results of our ongoing research and development efforts or products, if any, derived from our research program we must substantially expand our personnel, particularly in the areas of clinical trial management, regulatory affairs, business development and marketing. There can be no assurance that we will be successful in hiring or retaining qualified personnel. Managing the integration of new personnel and our growth generally could pose significant risks to our development and progress. The addition of such personnel may result in significant changes in our utilization of cash resources and our development schedule.

*We Expect To Operate In A Highly Competitive Market; We May Face Competition From Large, Well-Established Companies With Significant Resources; And, We May Not Be Able To Compete Effectively.*

Our commercial success will depend on our ability and the ability of our sublicensees, if any, to compete effectively in product development areas such as, but not limited to, safety, efficacy, ease of use, patient or customer compliance, price, and marketing and distribution. There can be no assurance that competitors will not succeed in developing products that are more effective than any products derived from our research and development efforts or that would render such products obsolete and non-competitive.

The biotechnology industry is characterized by intense competition, rapid product development and technological change. Most of the competition that we encounter will come from companies, research institutions and universities who are researching and developing technologies and potential products similar to or competitive with our own.

These companies enjoy numerous competitive advantages over us, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products.

*We May Become Subject To Claims Of Infringement Or Misappropriation Of The Intellectual Property Rights Of Others, Which Could Prohibit Us From Commercializing Products Based On Our Sponsored Research And Development Program, Require Us To Obtain Licenses From Third Parties Or To Develop Non-Infringing Alternatives, And Subject Us To Substantial Monetary Damages And Injunctive Relief.*

We do not have any patents regarding any of our sponsored research and development activities. We may not be able to assert any rights, under our CRADA, to any patents held by the USDA's Agriculture Research Service. Third parties could, in the future, assert infringement or misappropriation claims against us with respect to our current sponsored research and development program or future products, if any, derived from our sponsored research and development program. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties.

Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from continuing our research and development activities and from marketing or selling products, if any, derived from our sponsored research and development efforts unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to commercialize any products. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney

fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

*We May Be Exposed To Product Liability Claims For Which We Do Not Have Any Insurance Coverage.*

Because our activities involve the researching, developing and testing of new technologies; and in the future we may be involved either directly or indirectly in the manufacturing and distribution of products, if any, derived from our sponsored research and development efforts, we may be exposed to the financial risk of liability claims in the event that the use of any such product results in personal injury, misdiagnosis or death. We may be subject to claims against us even if the apparent injury is due to the actions of others. There can be no assurance that we will not experience losses due to product liability claims in the future, or that adequate insurance will be available in sufficient amounts, at an acceptable cost, or at all. A product liability claim, product recall or other claim, or claims for uninsured liabilities or in excess of insured liabilities, may have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers, or result in reduced acceptance of products derived from our sponsored research and development activities in the market.

We do not currently carry any insurance. If a claim against us results in a large monetary judgment, which we cannot pay, we may have to cease operations.

*Failure To Obtain Third Party Reimbursement For Products Derived From Our Sponsored Research and Development Efforts Could Limit Our Revenue.*

In the United States, success in obtaining payment for a new product from third parties, such as insurers, depends greatly on the ability to present data which demonstrates positive outcomes and reduced utilization of other products or services, as well as cost data which shows that treatment costs using the new product are equal to or less than what is currently covered for other products. If we are unable to obtain favorable third party reimbursement and patients are unwilling or unable to pay for such products or services out-of-pocket, it could limit our revenue and harm our business.

*Mr. Harmel S. Rayat, Our President, Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer And Director, Is Able To Substantially Influence All Matters Requiring Approval By Our Stockholders, Including The Election Of Directors.*

As of January 23, 2006, Mr. Rayat beneficially owned approximately 69% of our outstanding common stock. Accordingly, he is able to substantially influence virtually all matters requiring approval by our stockholders, including the election of directors. Our Articles of Incorporation do not provide for cumulative voting in the election of directors and, therefore, although they are able to vote, our other stockholders should not expect to be able to elect any directors to our board of directors.

*We Rely On Our Management, The Loss Of Whose Services Could Have A Material Adverse Affect On Our Business.*

We rely upon the services of our board of directors and management, in particular those of Mr. Harmel S. Rayat, the loss of which could have a material adverse affect on our business and prospects. Competition for qualified personnel to serve in a senior management position is intense. If we are not able to retain our directors and management, or attract other qualified personnel, we may not be able to fully implement our business strategy; failure to do so would have a materially adverse impact on our future prospects.

We currently have no employment agreements with any of our officers and directors imposing any specific condition on our officers and directors regarding their continued employment by us. Our officers and directors are also officers, directors and employees of other companies, and we may have to compete with such other companies for their time, attention and efforts. Except for Mr. Rayat, none of our officers and directors is expected to spend more than approximately five (5%) of his time on our business affairs. Mr. Rayat will not be spending his full

time and effort on our business affairs because he is engaged in other business activities. We do not expect Mr. Rayat to spend more than twenty (20%) of his time on our business affairs. If Mr. Rayat's other business activities, from time to time, require more of Mr. Rayat's time, he may have less time to spend on our business affairs and our operations could suffer as a result. We do not maintain key man insurance on any of our directors or officers.

*Future Sales Of Our Common Stock May Decrease Our Stock Price.*

We have previously issued a total of 70,439,183, shares of common stock, of which 55,039,683, are eligible for resale under Rule 144 of the Securities Act. In addition, we have also registered a substantial number of shares of common stock that are issuable upon the exercise of options. If holders of options choose to exercise their purchase rights and sell shares of common stock in the public market all at once or in a short time period, the prevailing market price for our common stock may decline. Future public sales of shares of common stock may adversely affect the market price of our common stock or our future ability to raise capital by offering equity securities.

*Our Stock Price Historically Has Been Volatile And May Continue To Be Volatile.*

The market price of our common stock has been and is expected to continue to be highly volatile. Factors, many of which are beyond our control, include, in addition to other risk factors described in this section, the announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, and general economic, industry and market conditions may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by our stockholders and by us, including Fusion Capital pursuant to this prospectus and subsequent sale of common stock by the holders options could have an adverse effect on the market price of our shares.

Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. To the extent our stock price fluctuates and/or remains low, it could cause you to lose some or all of your investment and impair our ability to raise capital through the offering of additional equity securities.

*Our Common Is A "Penny Stock" And Because "Penny Stock" Rules Will Apply, You May Find It Difficult To Sell The Shares Of Our Common Stock You Acquired In This Offering.*



Our common stock is a penny stock as that term is defined under Rule 3a51-1 of the Securities Exchange Act of 1934. Generally, a "penny stock" is a common stock that is not listed on a securities exchange and trades for less than \$5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stocks in start-up companies are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the U.S. Securities & Exchange Commission. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there is less trading activity in penny stock and you are likely to have difficulty selling your shares.

*Our Common Shares Are Thinly Traded, So You May Be Unable To Sell At Or Near Ask Prices Or At All If You Need To Sell Your Shares To Raise Money Or Otherwise Desire To Liquidate Your Shares.*

Our common shares have historically been sporadically or "thinly-traded" on the OTCBB, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. As of January 19, 2006, our average trading volume per day for the past three months was approximately 47,504 shares a day with a high of 246,300 shares traded and a low of 13,491 shares traded. This

situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

*Compliance With Changing Regulation Of Corporate Governance And Public Disclosure May Result In Additional Expenses.*

Keeping abreast of, and in compliance with, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and, in the event we are ever approved for listing on either NASDAQ or a registered exchange, NASDAQ and stock exchange rules, will require an increased amount of management attention and external resources. We intend to continue to invest all reasonably necessary resources to comply with evolving standards, which may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

*We Do Not Intend To Pay Dividends For The Foreseeable Future.*

We currently intend to retain future earnings, if any, to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize their investment. Investors seeking cash dividends should not purchase the units offered by us pursuant to this prospectus.

**ITEM 2. DESCRIPTION OF PROPERTY.**

Our principal office is currently located at 1628 West First Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. A private corporation controlled by Mr. Harmel S. Rayat, our president, chief executive and financial officer, principal accounting officer, director and majority stockholder, owns these premises; the premises are provided to us without charge. We share these facilities with several other companies with which Mr. Rayat is affiliated. This arrangement has been in place for all periods covered by the financial statements included in this

prospectus and has not had any adverse impact on our operations.

The only activities which we conduct at these premises relate solely to administrative and accounting functions, virtually all of which are computerized and require limited space and clerical assistance for their execution.

All of our sponsored research and development activities are conducted in facilities located at the Growth Biology Laboratory BARC-East, Bldg. 200, Room 202, Beltsville, Maryland 20705 and at the Biotechnology and Germplasm Laboratory BARC-East, Bldg. 200, Room 13, Beltsville, Maryland 20705. These facilities, which also include space for any support personnel that we may assign to the project, are provided to us under the terms of the CRADA.

We believe that in light of our current financial condition and level of activity, the Vancouver office is adequate and suffices for our general corporate and administrative operations, and the research and support facilities in Maryland are adequate for the current level of our sponsored research and development program. We intend to reassess, from time to time, our office and research facility requirements as the results of our research program and financing efforts may require.

**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

First Quarter 2005

\$4.97

\$2.38

Second Quarter 2005

\$3.12

\$1.80

Third Quarter 2005

\$2.10

\$1.40

Fourth Quarter 2005

\$2.20

\$1.35

As of January 19, 2006, there were approximately 63 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

Weighted-average exercise

future issuance under

be 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)

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Equity compensation plans

approved by security holders

13,833,000

\$0.39

26,925,000

Equity compensation plans not

approved by security holders

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Total

13,833,000

\$0.39

26,925,000



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

### Discussion and Analysis

*The following discussion and analysis is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, and should be read in conjunction with our financial statements and related notes. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In addition, the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, including, but not limited to, those discussed in Risk Factors, Forward Looking Statements, and elsewhere in this prospectus.*

### Overview

We are an early stage, research and development based, 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. We currently do not directly conduct any of our own research and development activities. Rather, once a technology has been identified, we fund the research and development activities relating to the technology with the intention of ultimately, if warranted, licensing, commercializing and marketing the subject technology.

Our sponsored research is being conducted pursuant to our CRADA with the USDA's Agricultural Research Service.

Currently, we are concentrating our efforts on developing an artificial liver device and in-vitro toxicology and pre-clinical drug testing platforms.

### Artificial Liver Device

We are working towards optimizing the hepatic functionality of a porcine cell line, and subclones thereof, which we refer to as the PICM-19 Cell Line. The PICM-19 Cell Line was developed and patented by USDA Agricultural Research Service scientists. The hepatic characteristics of the PICM-19 Cell Line have been demonstrated to have

potential application in the production of an artificial liver device. U.S. Patent #5,532,156 (Hepatocyte Cell Line Derived from the Epiblast of Pig Blastocysts ) was issued on July 2, 1996, and U.S. Patent 5,866,420 (Artificial liver device) was issued on February 2, 1999, both in the name of The United States of America as represented by the Secretary of Washington, DC.

#### In-Vitro Toxicology Testing

The PICM-19 Cell Line, grown in-vitro, can synthesize liver specific proteins such as albumin and transferrin and display enhanced liver-specific functions, such as ureagenesis (conversion to ammonia to urea) and cytochrome P450 activity. Consequently, we believe the PICM-19 Cell Line could be an important element in developing in-vitro toxicological and pre-clinical drug testing platforms that could more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

#### Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosures. We review our estimates on an ongoing basis.

We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. While our significant accounting policies are described in more detail in the notes to our financial statements included in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

#### General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel related costs, legal costs, including intellectual property, investor relations, accounting costs, and other professional and administrative costs.

#### Research and Development Costs

Research and development costs represent costs incurred to develop our technology incurred pursuant to our CRADA with the USDA's Agricultural Research Service and include salaries and benefits for research and development personnel, allocated overhead and facility occupancy costs, contract services and other costs. We charge all research and development expenses to operations as they are incurred. We do not track research and development expenses by project.

#### **Results of Operations**

We have yet to establish any history of profitable operations. We have not generated any revenues from operations during the past 5 years and do not expect to generate any revenues for the foreseeable future. We have incurred annual operating losses of \$1,435,613 and \$1,102,723, respectively, during the past two fiscal years of operation. As a result, at December 31, 2004, we had an accumulated deficit of \$3,747,771. Our profitability will require the successful completion of our research and development programs, and the subsequent commercialization of the results or of products derived from such research and development efforts. No assurances can be given when this will occur or that we will ever be profitable.

Our independent auditors have added an explanatory paragraph to their audit opinion issued in connection with the financial statements for the years ended December 31, 2004 and 2003, relative to our ability to continue as a going concern. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### Years Ended December 31, 2004 and 2003

We had no revenues in 2004 and 2003. Our general and administrative expenses increased 21% to \$1,285,988 in 2004, from \$1,062,270 in the same period in 2003. This increase was primarily attributable to an increase of \$56,913 in investor relations costs to \$1,016,916, as compared to \$960,003 in 2003 related primarily to fees paid to, and reimbursement of disbursements, inclusive of mailing costs, incurred by the Company's investor relations firm, National InfoSystems Inc., totaling \$1,016,916, as follows: aggregate monthly fees of \$ 68,563 to National InfoSystems; direct mail advertising costs of \$700,000; email advertising costs of \$234,353.and media marketing costs of \$14,000.

During the years ended December 31, 2004 and 2003, our investor relations costs represented approximately 71% and 87%, respectively, of our total expenses.

In 2004, we also incurred \$151,546 in research and development expenses, an increase of 266%, compared to \$41,400 of research and development costs that we incurred in 2003. The increase in research and development costs was the result of our making a total of three payments, consisting of two payments of \$65,423 (\$130,846 in the aggregate) and one payment of \$20,700, under our CRADA.

Interest income increased 103% to \$1,921 in 2004, from \$947 during the same period in 2003. This was the result of higher average cash balances maintained during 2004.

Our net loss in 2004 increased 30% to \$1,435,613, from \$1,102,723 in 2003. The increase in our net loss was principally caused by increased research and development expenses and investor relations costs as noted above.

Our operations in 2004 were funded from net loan proceeds in the amount of \$275,000 from Mr. Harmel S. Rayat, and \$1,391,620 from the proceeds from the sale of our common stock upon exercise of outstanding options and warrants. In addition, at December 31, 2004, we had a net operating loss carry forward for federal income tax purposes of approximately \$570,000, which expires at various dates through 2024. The extent of any potential tax benefits to us from the operating loss carry forward is not presently ascertainable.

### 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.

In addition, as of the date of this amendment, pursuant to our common stock purchase agreement with Fusion Capital, we have the right to receive \$25,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds \$1.00, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.50. Since we initially registered 10,000,000 shares for sale by Fusion Capital pursuant to this prospectus, the selling price of our common stock to Fusion Capital will have to average at least \$1.50 per share for us to receive the maximum proceeds of \$15.0 million without registering additional shares of common stock. Assuming a purchase price of \$1.37 per share (the closing sale price of the common stock on January 19, 2006) and the purchase by Fusion Capital of 10,000,000 shares under the common stock purchase agreement, proceeds to us would be \$13,700,000. Subject to approval by our board of directors, we have the right but not the obligation to issue more than 10,000,000 shares to Fusion Capital. In the event we elect to issue more than 10,000,000 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the U.S. Securities & Exchange Commission.

Although we believe that we have sufficient cash on hand to satisfy our contractual commitments through February 28, 2006, we do not currently have sufficient cash on hand to sustain planned operating activities through the end of

2006. Our ability to continue as a going concern is substantially dependent upon future levels of funding from our funding sources, including Fusion Capital, which are currently uncertain as to amount and timing. Specifically, Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.50. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell products, if any, derived from our research and development efforts, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$15.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would be a material adverse effect on our business, operating results, financial condition and prospects. We have no agreements or understandings with any other person regarding any potential financing. The extent to which we will rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the number of shares outstanding, progress we have made in our business, other opportunities we may wish to pursue, general economic conditions, our capital requirements at the time, and the extent to which we are able to secure working capital from other sources on terms that are more beneficial to us.

At this time, except for our agreement with Fusion Capital, we have no agreements or understandings with any third party regarding any financings.

## Cooperative Agreement

On November 1, 2002, we entered into a CRADA with the USDA's Agricultural Research Service and committed to pay a total of \$292,727 to USDA's Agricultural Research Service over a two-year period ending February 19, 2005.

On May 24, 2004, we amended the CRADA, and agreed to pay a total of \$807,828 through September 30, 2007, of which \$153,600 had already been paid under the original agreement.

Effective on November 28, 2002, we amended our CRADA, in writing, to provide for the addition of Dr. Thomas Caperna as a co authorized departmental officer's designated representative.

Effective on July 12, 2003, we amended our CRADA, in writing, to reflect the change of our name from Zeta Corporation to Hepalife Technologies, Inc.

In February 2004, we orally amended our CRADA to modify the payment schedule so as to delay payment of installments due in August and November of 2004 and thereafter until and unless funds are actually required.

### Contractual Responsibilities under the CRADA

Under the terms of the CRADA, as amended, the USDA's Agricultural Research Service is responsible for:

- Hiring one post-doctoral research associate, one support scientist, and one technician for a 2 to 3 year period.
- Providing laboratory and office space for the research associate.
- Providing a fully equipped cell culture laboratory and protein chemistry laboratory.
- Providing experimental animals (pigs) and slaughter facilities.

- Acquiring specific laboratory equipment, e.g., rotating cell culture system and supplies to conduct the CRADA objectives.
- Conducting research on the optimization of the PICM-19 Cell Line, or its derivative cell lines (or related pig epiblast-derived cell lines), as an in-vitro pig liver cell model, and adapt the PICM-19 liver Cell Line technology to an extracorporeal liver assist device and to in-vitro formats for metabolic, toxicological, and carcinogenicity assay.
- Preparing progress reports on project objectives.
- Preparing and submit technical reports for publication.
- Providing access to 1850 square feet of laboratory space in the Beltsville Agricultural Research Center for our personnel assigned to work on the project.
- Providing utilities, services, and general support to our personnel, on an as needed and available basis.

We, in turn, our responsible for:

- Providing funds for one post-doctoral research associate, one support scientist, and one technician for a 2 to 3 year period.
- Providing funds for project related laboratory equipment, supplies, and off site research services such as electron microscopy and bioreactor component manufacturing.
- Providing funds for position advertisement and travel expenses for position interviews.





- Providing funds for professional activities of research associate such as travel to meetings and project specific training activities.

- Preparing and filing patent applications.

Generally, the terms of the CRADA also require our interaction with USDA's Agricultural Research Service 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. There has not been any material change in the relative responsibilities of the parties to the CRADA since its execution.

Payment Requirements and Budget Under the CRADA

Under the terms of the CRADA, we are obligated to make payments aggregating \$807,828.00 to the USDA's Agricultural Research Service over the term of the CRADA, as listed below:

**Amount**

**Date Due**

\$65,422.80

on or before August 1, 2004;

\$65,422.80

on or before November 1, 2004;

\$65,422.80

on or before February 1, 2005;

\$65,422.80

on or before May 1, 2005;

\$65,422.80

on or before August 1, 2005;

\$65,422.80

on or before November 1, 2005;

\$65,422.80

on or before February 1, 2006;

\$65,422.80

on or before May 1, 2006;

\$65,422.80

on or before August 1, 2006;

\$65,422.80

on or before November 1, 2006

In February 2004, we orally amended our CRADA to modify the payment schedule so as to delay payment of installments due in August and November of 2004 and thereafter until and unless funds are actually required.

The payments are to fund salaries, equipment, travel and other indirect costs of one post-doctoral researcher, one support scientist, and one technician up to September 30, 2007, as well as funds for the associated laboratory supplies and professional activities involved with conducting the CRADA objectives.

More specifically the agreed to budget for the CRADA contemplates the expenditure of these funds substantially as follows:

<b>BUDGET CATEGORY</b>	<b>AMOUNT</b>
A. Salaries and Wages	\$408,400.00
B. Equipment	\$28,025.00
C. Materials and Supplies	\$265,500.00
D. Travel	
1. Domestic	\$14,000.00
2. Foreign	
E. Facilities	-0-
F. Other Direct Costs	\$11,126.00
G. TOTAL DIRECT COSTS	\$727,051.00

H. Indirect Costs	\$80,777.00
I. TOTAL COSTS	\$807,828.00

Research Objectives of the CRADA.

The initial research objectives of the CRADA included:

-

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

As of the date of this 10-KSB/A, the PICM-19 Cell Line has been assayed for its response to several specific growth factors and cell attachment factors. Two specific growth stimulating factors have been identified and two attachment factors that enable the attachment and maintenance of the PICM-19 Cell Lines have been identified.

-

Developing spheroid cultures (self-assembling balls of cells) of the PICM-19 Cell Line without STO feeder cells and testing of rotating cell culture system for production and maintenance of spheroids.

As of the date of this 10-KSB/A, this objective has been redirected to the testing of PICM-19 Cell Line growth and maintenance on various types of commercially available glass or plastic micro- and macro-spheres. One type each of plastic microsphere and macrosphere has been successfully tested and are now in use in a model flow-through bioreactor that is currently in its testing phase.

-

Investigating effects of accessory cells obtained from pig liver on the PICM-19 Cell Line growth, differentiation, and metabolic function.

As of the date of this 10-KSB/A, these studies are not anticipated to be necessary for completion of the CRADA objectives and accordingly, are not longer deemed a priority.

-

Assaying the PICM-19 Cell Line and spheroids for liver specific functions by measuring P450 activity, liver enzyme activities, urea production, and ammonia clearance.

As of the date of this 10-KSB/A, P450 activity, urea production, and ammonia clearance activity of the PICM-19 cell line and three derivative cell lines (PICM-19H, PICM-19-3BT, PICM-19HA) have been confirmed and completed. Gamma-glutamyltranspeptidase enzyme (a key bile duct enzyme for the processing of inflammatory and anti-inflammatory molecules) activity has been confirmed and completed in the PICM-19 cell line and in two of the three PICM-19 derivative cell lines. Gamma-glutamylcysteine synthetase (a secondary detoxification liver enzyme) activity assays are on-going.

-

Assaying the PICM-19 Cell Line liver specific protein synthesis and secretion by protein

identification techniques. As of the date of this prospectus, liver specific protein synthesis by the PICM-19 cell line has been completed. Several liver specific proteins secreted by the PICM-19 cells were identified by Western blotting, 2-D gel electrophoresis, and mass spectrophotometric analysis.

-

Developing and testing, by in-vitro assay, flow-through bioreactors that enable the growth, differentiation, and maintenance of metabolic function of the PICM-19 Cell Line, or its derivative cell lines, over long term culture (1-3 months). As of the date of this prospectus, three flow-through bioreactor model systems incorporating the PICM-19 cells are being tested for cell viability, ammonia clearance activity, P450 enzyme activity, and urea production activity.

-

Developing and testing multi-well cell culture formats for the in-vitro assay of the effects of various test compounds on the metabolism and viability of the PICM-19 Cell Line derived hepatocytes or bile ductules (liver cell channels).

As of the date of this 10-KSB/A, multi-cell cell culture formats have been successfully tested and P-450 enzyme assays are currently being tested and standardized in 6-well, 24-well, and 96-well formats.

-

Genetically engineering the PICM-19 Cell Line 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.

As of the date of this 10-KSB/A, STO cell lines have been created by genetic engineering that express GFP and the neomycin-resistance gene. The construction of GFP and RFP (red fluorescent protein) mammalian expression vectors under the control of the alpha-fetoprotein promoter is currently underway for use in the genetic engineering of the PICM-19 Cell Line.

-

Developing cell transformation assay formats to demonstrate and enable the utilization of the PICM-19 Cell Line for the study of mutagenic or carcinogenic processes.

As of the date of this 10-KSB/A, this aspect of the CRADA has the lowest priority and no work is anticipated on this aspect of the project for at least two years.

#### Ownership of Developed Technologies Under the CRADA

Under the terms of the CRADA all rights, title and interest in any subject invention made solely by USDA's Agricultural Research Service employees are owned by USDA's Agricultural Research Service, solely by us are owned by us, and any such inventions are owned jointly by us and USDA's Agricultural Research Service if made jointly by USDA's Agricultural Research Service and us. Under the CRADA, we have an option to negotiate an exclusive license in each subject invention owned or co-owned by USDA's Agricultural Research Service for one or more field (s) of use encompassed by the CRADA. The option terminates when and if we fail to:

- submit a complete application for an exclusive license within sixty days of being notified by USDA's Agricultural Research Service of an invention being available for licensing; or

- submit a good faith written response to a written proposal of licensing terms within forty five days of such proposal.

The USDA's Agricultural Research Service has the first option to prepare and prosecute patent or Plant Variety Protection Certificate applications, on subject inventions that are owned or co-owned by the USDA's Agricultural Research Service, which option may be waived in whole or in part.

Although the termination date of the CRADA is September 30, 2007, the CRADA is subject to earlier termination at any time by mutual consent. Moreover, 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. To date, we have neither given nor received any such written notice.

## **Plan of Operation**

The essential elements of our business plan are centered upon the utilization of the PICM-19 Cell Line in two separate biomedical applications, namely the development of an artificial liver device and in vitro toxicological testing platforms.

### *Artificial Liver Device*

To help liver failure patients survive long enough to receive a liver transplant or recover without a transplant by exploiting 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 as a consequence of problems relating to their inability to grow liver cells quickly and safely and with inconsistent results from filtering devices. Culturing and maintaining such cells have proven difficult; once removed from the body, they soon lose their normal functioning attributes.



To date, the cellular components of artificial liver devices that are being tested have been based on freshly isolated porcine hepatocytes (liver cells), human immortal 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 device is the lack of an appropriately defined cell line that will provide the functions of an intact liver.

We are working towards optimizing the hepatic (liver) functionality of a porcine cell line and subclones thereof, which we refer to as the PICM-19 Cell Line. The PICM-19 Cell Line was developed and patented by USDA Agricultural Research Service scientists. Thus far, we have demonstrated that cells from the PICM-19 Cell Line are highly metabolic and are capable of clearing toxic levels of ammonia from the culture environment in a static culture system (ammonia is a highly toxic molecule and a major causative agent of hepatic coma in patients with acute liver failure). A unique metabolic feature of PICM-19 cells is also the production of urea, which is the product of an enzymatic pathway only present in hepatocytes and which is not found in any hepatic tumor cell lines.

Based upon our assessment of the information and data obtained in connection with our decision to enter into the CRADA and subsequently obtained from our ongoing sponsored research efforts, we believe the PICM-19 Cell Line has the required attributes to address the need for an appropriately defined cell line for incorporation into an artificial liver device. Key among these attributes is the PICM-19 Cell Line's ability to differentiate into bile duct cells and hepatocytes (which comprise most of the liver and perform the vital metabolic and detoxification functions of the liver), which have been shown to have several liver specific functions such as the production of serum proteins and P450 enzymes (the key components in the overall hepatic detoxification pathway of drugs and other xenobiotics or foreign substances).

In our view, additional advantages of the PICM-19 Cell Line include, but are not limited to:

-

the PICM-19 Cell Line is not tumor-causing, a feature not only critical to nutrient metabolism research, but one which the cell line has retained even after years in continuous culture;

-

the PICM-19 Cell Line does what other cell lines do not do; it stops dividing and matures into functioning hepatocytes or bile ducts as normal cells do in the body (i.e., not cancerous in nature);

-

because the PICM-19 Cell Line is a cell line, it will grow (divide in two) over and over again so that a potentially unlimited number of cells can be created;

-

the ability of the PICM-19 Cell Line to continuously increase in number means that the cells can be studied to "define" their stability of form and function and defined also in being free of harmful agents such as toxins, viruses, bacteria, and fungi;

-

because the PICM-19 Cell Line is a growing population of cells, individuals (cells) within the population that have superior attributes can be searched for and isolated;

-

current methods of genetic engineering can be applied to the cells for the creation of derivative cell lines which are more advantageous in various ways for incorporation into an artificial liver device, and finally,

-

the PICM-19 Cell Line could also be useful for toxicological studies as an alternative to animal testing where specific information is needed on how toxic various substances are to liver and bile duct cells.

As a result of these hepatic characteristics and advantages noted above, we believe the PICM-19 Cell Line, and subclones thereof, has potential application in the production of an artificial liver device, which application was also developed and patented by USDA Agricultural Research Service scientists for potential use by human patients with liver failure.

The subclone of the PICM-19 Cell Line that is in current use (PICM-19H) has been in continuous culture for more than three years and has been passaged (subdivided and expanded) over 120 times. These cells have been selected and defined with respect to their rapid growth capacity and their liver cell function. A recently discovered significant feature of the cell line is its ability to maintain function after storage at room temperature for greater than 1 week. This will aid in the shipment and storage of bioreactors, devices which could house and maintain liver cells. All current available data has been attained from PICM-19H cells grown in a monolayer cell culture format with static growth medium. Therefore, it is imperative to research and develop the means to grow the cells in a three dimensional format so that the bioreactor will provide enough surface area for effective interaction with a patient's plasma. Experiments assessing the growth and function of the PICM-19H cells using a variety of known three dimensional cell matrices is under current investigation. In addition, model bioreactors are currently being tested for flow dynamics and the effects of flowing growth medium on the morphology and function of the PICM-19H cells.

All of our sponsored research objectives relate to optimization and definition of the PICM-19 Cell Line, and subclones thereof, with respect to applications and use in an artificial liver device or for toxicity testing. These include evaluation of:

-

Attachment, growth and metabolism of PICM-19 cells on porous and semi-porous substrates such as microcarrier beads;

-

Various coatings and attachment factors in conjunction with matrix materials;

-

Genetic and metabolic stability of the cells over time;

-

Characteristics of the cells in model flow-through culture systems;

-

Metabolic integrity of the cells in the presence of specific-disease-state human plasma;

-

Optimum age of cultures to obtain the highest metabolic activity;

-

Bioreactor design parameters, including optimization of flow, sheer force, media components and oxygen input;

-

Optimum conditions for the induction and measurement of known P450 enzymes and other detoxification enzymes in multi-well plates;

-

Potential for inserting a reporter gene system into the genome to facilitate rapid-high through-put toxicity testing, and

-

Novel co-culture systems to address potential toxic interactions among different

cell types.

There is no assurance that we will achieve all or any of our goals.

### *In Vitro Toxicology and Drug Testing*

Hepatocytes, the major cell type comprising 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.

We believe the ability of the PICM-19 Cell Line, which is also concurrently being tested by us for use in an artificial liver device, to differentiate into either hepatocytes or bile duct cells (two key cell types of the liver) and to synthesize liver specific proteins, such as albumin and transferrin, as well as display enhanced liver-specific functions, such as ureagenesis and cytochrome P450 activity, could be important to the development of in-vitro toxicological and pre-clinical drug testing platforms that could more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

According to FDA recommendations, all drugs and newly developed chemicals require rigorous toxicity testing before approval can be granted. Since the liver is the primary site of chemical detoxification as well as the tissue where many compounds are activated into highly toxic substances, much attention has been placed upon development of an in-vitro model liver system for drug testing. Currently available test systems utilize either cells isolated from rat, pig or human livers or use available tumor cell lines or proprietary modified tumor cell lines. Ultimately, these systems lack either stability, reproducibility (primary cell isolates) or the ability to fully represent the complete set of hepatic functions (tumor cell lines). These drawbacks do not appear to exist with the PICM-19H cell line as these cells were naturally derived from porcine embryonic stem cells and have demonstrated functional stability in long term culture. We could supply plates (96-, 24-, 12-, or 6- well formats) of PICM-19H cells to clients who wish to run their in-house toxicity tests. Alternatively, standard in-house tests could be performed using client-provided test substances. In the latter case, data would be collected, and analyzed by our staff on a fee- for-service basis. Current posted prices for providing a fully confluent 96 well plate of tumor cells designed for toxicity testing is approximately \$500.

We are currently establishing toxicity testing profiles of the PICM-19H cells in multi-well plate formats to provide baseline data of specific liver function responses for the cell line. This data will enable potential interested users, e.g., pharmacology and chemical companies, to assess the potential utility of the PICM-19H cells in an in-vitro liver function system for their drug or chemical metabolic profiling needs. Known inducers of detoxifier proteins (P-450 enzymes) are being used to test and compare the responses of PICM-19H cells to known animal data and other



available liver cell lines. The ability of the cells to form secondary detoxified products and to make urea (a non-toxic product of ammonia metabolism) is currently being characterized.

Due to the "start up" nature of our business, we expect to incur losses as we continue conducting our ongoing sponsored 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.

## **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 meeting held on May 28, 2003, our board of directors agreed to accept a loan commitment from Mr. Harmel S. Rayat, a director and our major stockholder agreed to loan us up to \$750,000 on an as needed basis. The commitment has subsequently increased to \$1,600,000. Proceeds from the loan are to fund our research and development commitments, legal and audit fees, ongoing investor and public relations costs and other working capital requirements.

In 2003, we drew down \$725,000; the loan was reflected by unsecured promissory notes bearing interest at rates ranging from 7.00% to 7.25%. These notes and accrued and unpaid interest in the amount of \$51,500 were paid in 2004.

On August 27, 2004, we again 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. On December 31, 2004 there was accrued and unpaid interest on the note of \$7,187 is included in accounts payable. This note was repaid in January of 2005.

In December 2004, Mr. Rayat advanced, on our behalf, \$700,000. We issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

In March 2005, Mr. Rayat advanced, on our behalf, \$250,000. We issued an unsecured promissory note bearing interest at a rate of 8.50 % due on March 8, 2006.

In December 2005, Mr. Rayat advanced, on our behalf, \$200,000. We issued an unsecured promissory note bearing interest at a rate of 8.50 % due on December 5, 2006.

On January 18, 2006, we agreed, in consideration of Mr. Rayat's oral undertaking to increase his loan commitment to us up by an additional \$100,000, to \$1,600,000, to convert all of the loans to demand loans. The notes are due and payable upon the receipt of written demand from Mr. Rayat.

The loans bear interest at the rate of 8.50% per annum. We do not currently have sufficient capital on hand to repay these loans. We may prepay these loans, at any time, without penalty. We expect to repay these amounts from the proceeds, if any, we receive under the common stock purchase agreement with Fusion Capital. There is no assurance that we will be able to repay all or a part of these loans or obtain any additional loans from Mr. Rayat in the event we do not receive the proceeds from Fusion Capital.

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

(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 7. FINANCIAL STATEMENTS.**

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**MOORE STEPHENS**

**ELLIS FOSTER LTD.**

CHARTERED ACCOUNTANTS

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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, 2002 were audited by other auditors whose report, dated March 3, 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

**2002 AUDITOR LETTER**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Hepalife Technologies, Inc. (formerly Zeta Corporation)

We have audited the accompanying statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2002 and the cumulative data from October 21, 1997 (inception) to December 31, 2002, of Hepalife Technologies, Inc. (formerly Zeta Corporation) (a development stage company, the Company), a Florida Corporation. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these statements based on our audit.

We conducted our audit, in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about 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 provides a reasonable basis for our opinion.

In our opinion the financial statements referred to above present fairly, in all material respects, the Company's results of operations and its cash flows for the year ended December 31, 2002, and the cumulative data from October 21, 1997 (inception) to December 31, 2002, in conformity with generally accepted accounting principles in the United States.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 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 inception resulting in a substantial accumulated deficit. The Company is devoting substantially all of its present efforts in establishing its business. Management's plans regarding the matters that raise substantial doubt about the Company's ability to continue as a going concern are also disclosed in Note 2 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 factors raise substantial doubt about its ability to continue as a going concern. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Clancy and Co., P.L.L.C.

Phoenix, Arizona

March 3, 2003

**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)
<b>Total liabilities and stockholders' equity</b>	<b>\$ 614,351</b>

**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)**

	Common shares		Additional paid-in capital	Loss accumulated during development stage	Total stock- holders' equity (deficiency)
	Shares	Amount			
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
<b>Balance</b> , 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)	-	-	-	(471,988)	(471,988)

Loss, year ended December 31,  
1998

<b>Balance</b> , 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)
<b>Balance</b> , 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)
<b>Balance</b> , December 31, 2000	41,200,000	41,200	736,800	(673,599)	104,401
<b>Balance</b> , 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)
<b>Balance</b> , 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)
<b>Balance</b> , 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)					
Loss, year ended December 31, 2003	-	-	-	(1,102,723)	(1,102,723)
<b>Balance</b> , 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			(1,435,613)	(1,435,613)
<b>Balance, December 31, 2004</b>	67,817,832	\$ 67,818	\$ 3,141,002	\$ (3,747,771) \$ (538,951)

**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 December 31 2004	Year ended December 31 2003
<b>General and administrative expenses</b>			
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>	<b>(3,780,106)</b>	<b>(1,437,534)</b>	<b>(1,103,670)</b>

**Other income**

Interest income	32,335	1,921	947
-----------------	--------	-------	-----

<b>Net (loss) for the year</b>	<b>\$ (3,747,771)</b>	<b>\$ (1,435,613)</b>	<b>\$ (1,102,723)</b>
--------------------------------	-----------------------	-----------------------	-----------------------

**Loss per share of common stock**

- basic and diluted		\$ (0.02)	\$ (0.019)
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**Basic weighted average number  
of common stock outstanding**

- basic and diluted		64,610,777	57,817,305
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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)

## Statements of Cash Flows

**(Expressed in U.S. Dollars)**

	Cumulative Amount Since Inception to December 31 2004	Year ended December 31 2004	Year ended December 31 2003
<b>Cash flows from (used in)</b>			
<b>operating activities</b>			
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)
<b>Cash flows used in</b>			
<b>investing activities</b>			
Purchase of equipment	(4,560)	(1,089)	-
Net cash used in investing activities	(4,560)	(1,089)	-
<b>Cash flows from (used in) financing activities</b>			



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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
<b>Increase in cash and cash equivalents</b>	613,523	301,322	283,599
<b>Cash and cash equivalents, beginning of year</b>	-	312,201	28,602
<b>Cash and cash equivalents, end of year</b>	\$ 613,523	\$ 613,523	\$ 312,201
<b>Supplemental non-cash investing and financing activities:</b>			
Conversion of debt to equity	\$ 338,000	\$ -	\$ -
Common stock issued for services rendered	\$ 523,100	\$ -	\$ -
<b>Supplemental cash flow information:</b>			
Interest paid by cash	\$ 51,909	\$ 51,909	\$ -
Income tax paid by cash	\$ -	\$ -	\$ -

**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 does not differ materially from basic 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.

(l)

#### 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 Financial 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.

(o)

#### 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:

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

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:

	Shares	Weighted Average 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

Options Outstanding and Exercisable

Range of Exercise Prices	Number Outstanding	Number exercisable	Weighted Average Remaining Contractual Life (yr.)	Weighted Average Exercise 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:

	2004	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 in 2003 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:

2004

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.**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

An evaluation was performed under the supervision of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Securities Exchange Act of 1934 (the Exchange Act) Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act (a) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes in internal controls, or in factors that could materially affect internal controls, subsequent to the date that management, including the Chief Executive Officer and the Chief Financial Officer, completed their evaluation.

**ITEM 8B. OTHER INFORMATION.**

None.

### PART III

#### **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 our directors and officers, and the positions held by each, as at December 31, 2004. On August 12, 2005, Mr. Harmel S. Rayat was appointed our president, chief executive officer, chief financial officer, and principal accounting officer; and Mr. Soheili resigned as our president and chief executive officer and assumed positions as our secretary and treasurer on the same day.

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.

Except as set forth below, none of the corporations or organizations with whom our directors are affiliated with is a parent, subsidiary or other affiliate of ours. Mr. Rayat is an officer, director and majority stockholder of each of Phytomedical Technologies, Inc., Entheos Technologies, Inc. and International Energy, Inc.

There are no family relationships among or between any of our officers and directors.

There are no arrangements or understandings between him and any other person(s) (naming such person(s)) pursuant to which he was or is to be selected as a director or nominee.

Except as set forth below, during the past five years none of our directors, executive officers, promoters or control persons have been:

(a)

the subject of any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

(b)

convicted in a criminal proceeding or is subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

(c)

subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or

(d)

found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law.

Mr. Harmel S. Rayat, EquityAlert.com, Inc., Innotech Corporation and Mr. Bhupinder S. Mann, a former part-time employee of ours (collectively the respondents), consented to a cease-and-desist order pursuant to Section 8A of the Securities Act of 1933. The matter related to the public resale by EquityAlert of securities received as compensation from or on behalf of issuers for whom EquityAlert and Innotech provided public relation and stock advertising services; Mr. Rayat was the president of Innotech and Equity Alert was the wholly-owned subsidiary of Innotech at the time.

The U.S. Securities & Exchange Commission contended and alleged that Equity Alert had received the securities from persons controlling or controlled by the issuer of the securities, or under direct or indirect common control with such issuer with a view toward further distribution to the public; as a result, the U.S. Securities & Exchange Commission further alleged that the securities that Equity Alert had received were restricted securities, not exempt from registration, and hence could not be resold to the public within a year of their receipt absent registration; and, accordingly, the U.S. Securities & Exchange Commission further alleged, since Equity Alert effected the resale within a year of its acquisition of the securities, without registration, such resale violated Sections 5(a) and 5(c) of the Securities Act.

Without admitting or denying any of the findings and/or allegations of the U.S. Securities & Exchange Commission the respondents agreed, on October 23, 2003 to cease and desist, among other things, 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 U.S. Securities & Exchange Commission that EquityAlert 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, among other things, violating Section 17(b) of the Securities Act of 1933; in addition, each of Mr. Rayat and EquityAlert 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 our 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 us 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 us, we believe 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

All Other

Principal Position      Year      Salary

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

\$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.

Currently, we pay our directors for their services as directors a monthly stipend of \$250 per month, with the exception of Mr. Rayat, who since becoming our president on August 12, 2005, has not received any compensation for services rendered as a director. In addition, each director receives \$100 per board or committee meeting attended. We have no other arrangements pursuant to which any our directors was compensated during the year ended December 31, 2004 and 2003, for services as a director.

#### 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

Name

Options

in 2004

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

Name

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

51

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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 January 23, 2006, 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)

53,463,056

69%

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

69%

as a group (3 persons)

(1) 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. Also 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. Mr. Rayat disclaims beneficial ownership of the shares beneficially owned by his other family members.

## **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 meeting held on May 28, 2003, our board of directors agreed to accept a loan commitment from Mr. Harmel S. Rayat, a director and our major stockholder agreed to loan us up to \$750,000 on an as needed basis. The commitment has subsequently increased to \$1,600,000. Proceeds from the loan are to fund our research and development commitments, legal and audit fees, ongoing investor and public relations costs and other working capital requirements.

In 2003, we drew down \$725,000; the loan was reflected by unsecured promissory notes bearing interest at rates

ranging from 7.00% to 7.25%. These notes and accrued and unpaid interest in the amount of \$51,500 were paid in 2004.

On August 27, 2004, we again 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. On December 31, 2004 there was accrued and unpaid interest on the note of \$7,187 is included in accounts payable. This note was repaid in January of 2005.

In December 2004, Mr. Rayat advanced, on our behalf, \$700,000. We issued an unsecured promissory note bearing interest at a rate of prime plus 3% per annum and due on September 1, 2006.

In March 2005, Mr. Rayat advanced, on our behalf, \$250,000. We issued an unsecured promissory note bearing interest at a rate of 8.50 % due on March 8, 2006.

In December 2005, Mr. Rayat advanced, on our behalf, \$200,000. We issued an unsecured promissory note bearing interest at a rate of 8.50 % due on December 5, 2006.

On January 18, 2006, we agreed, in consideration of Mr. Rayat's oral undertaking to increase his loan commitment to us up by an additional \$100,000, to \$1,600,000, to convert all of the loans to demand loans. The notes are due and payable upon the receipt of written demand from Mr. Rayat.

The loans bear interest at the rate of 8.50% per annum. We do not currently have sufficient capital on hand to repay these loans. We may prepay these loans, at any time, without penalty. We expect to repay these amounts from the proceeds, if any, we receive under the common stock purchase agreement with Fusion Capital. There is no assurance that we will be able to repay all or a part of these loans or obtain any additional loans from Mr. Rayat in the event we do not receive the proceeds from Fusion Capital.

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

(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)

31.2

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

32.1

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

32.2

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

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

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

December 15, 2004: 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 our 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 us for tax compliance, tax advice and tax planning by our principal accountant for fiscal 2004 and 2003 were \$0.

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

We do 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 amendment to its report on Form 10KSB for the fiscal year ended December 31, 2004, to be signed on its behalf by the undersigned, thereunto duly authorized on this 8th day of February, 2006.

HepaLife Technologies, Inc.

/s/ Harmel S. Rayat

Harmel S. Rayat

Chief Executive Officer

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



Signature

Title

Date

/s/ Harmel S. Rayat

Director , President,

February 8, 2006

Harmel S. Rayat

Chief Executive Officer

/s/ Jasvir Kheleh

Director

February 8, 2006

Jasvir Kheleh

/s/ Arian Soheili

Director, Secretary/Treasurer,

February 8, 2006

Arian Soheili

Principal Financial Officer

