HEPALIFE TECHNOLOGIES INC
Form 10-K
March 31, 2009

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

FORM 10-K

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

For the fiscal year ended December 31, 2008

OR

o 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.)

60 State Street, Suite 700, Boston, MA 02109
(Address of principal executive offices)

(800) 518-4879
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value per share
(Title of Each Class)

Over The Counter Bulletin Board (OTCBB)
(Name of exchange on which registered)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No T

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 of Section 15(d) of the Act. Yes £ No T

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 T No £

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (229.405 of this chapter) 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-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	£	Accelerated filer	£
Non-accelerated filer (Do not check if a smaller reporting company)	£	Smaller reporting company	T

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes £ No T

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant’s most recently completed second fiscal quarter, based upon the closing sale price of the registrant’s common stock on June 30, 2008: $26,445,762.

Number of shares of Common Stock, $0.001 par value, outstanding as of March 20, 2009: 91,996,829.

Documents incorporated by reference: None.

TABLE OF CONTENTS

HEPALIFE TECHNOLOGIES, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

Table of Contents

PART I

ITEM 1. BUSINESS.

Forward-Looking Statements

Except for the historical information presented in this document, the matters discussed in this Form 10-K for the fiscal year ending December 31, 2008, contain 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,” “could,” “might,” “expect,” “anticipate,” “estimate,” “believe,” “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 of Financial Condition and Results of Operations,” “Business,” “Properties,” as well as in this report generally.

The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by the Company. The reader is cautioned that no statements contained in this Form 10-K should be construed as a guarantee or assurance of future performance or results. 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 described in this report 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. These forward-looking statements are based on current expectations, and the Company assumes no obligation to update this information. Readers are urged to carefully review and consider the various disclosures made by the Company in this Form 10-K and in the Company's other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks and factors that may affect the Company's business.

The Company

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 91,996,829 were issued and outstanding on March 20, 2009) and 1,000,000 shares of preferred stock (none of which has been issued).

Our principal executive offices are located at 60 State Street, Suite 700, Boston, MA 02109. Our telephone number is 800-518-4879. The address of our website is www.hepalife.com. Information on our website is not part of this Form 10-K.

Because we are a smaller reporting company, certain disclosures otherwise required to be made in a Form 10-K are not required to be made by the Company.

Description of Business

We are a development stage biotechnology company. 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. On December 31, 2008, we had an accumulated deficit of $19.3 million.

We are currently focused on the development of HepaMate™, a cell-based bioartificial liver system, as a potential treatment for liver failure patients. HepaMate™ is designed to provide whole liver function in patients with the most severe forms of liver failure by combining the process of removing toxins from the patient's blood (detoxification) with concurrent liver cell therapy. HepaMate™ has been successfully tested in a clinical Phase I study and was previously known as "HepatAssist".

We acquired the HepatAssist technology and related assets from Arbios Systems, Inc. ("Arbios") in October 2008, as part of our ongoing efforts to enhance and strengthen our bioartificial liver development program. The assets we acquired (collectively, the "HepatAssist Related Assets") from Arbios, include: over 12 patents and patent licenses; miscellaneous scientific equipment; United States Food and Drug Administration ("FDA") Investigative New Drug application, including orphan drug and fast track designation; Phase I and Phase II/III clinical protocols and clinical data; and standard operating procedures for manufacturing and quality control. The HepatAssist related Assets relate to the bioartificial liver device formerly known as "HepatAssist," now referred to as "HepaMate™."

Table of Contents

We are currently working towards optimizing our HepaMate™ bioartificial liver device for utilization in a new clinical Phase III study followed, if warranted, by commercialization upon final regulatory approval.

Prior to our acquisition of the HepatAssist Related Assets from Arbios, we focused our efforts on the research and development of: a porcine stem cell line, and subclones thereof, which we refer to as the "PICM-19 cell line" for use in a bioartificial liver and in-vitro toxicology testing; and on the development and potential commercialization of a chicken cell line, and subclones thereof, which we refer to as the "PBS-1 cell line."

The PICM-19 cell line has been developed for potential use in a bioartificial liver device and in-vitro toxicology platforms, and was exclusively licensed from the U.S. Department of Agriculture, Agricultural Research Service ("USDA, ARS") in November 2007. In September 2008, the license was amended in order to expand the field-of-use to allow for use of the PICM-19 cell line as in-vitro infection host systems for viral and protozoan agents such as malaria. We are continuing to evaluate the further optimization of our PICM-19 liver stem cell line.

The PBS-1 cell line was developed for potential use in cell-based vaccine production and was exclusively licensed from Michigan State University ("MSU") in June 2006. In January 2009, we provided written notice to MSU terminating the license agreement effective April 24, 2009.

HepaMate™ Bioartificial Liver System

We are developing HepaMate™ for patients with acute or severe liver failure. HepaMate™ is the most clinically-studied bioartificial liver with more than 50 scientific papers and book chapters published on the technology. Over 200 patients have participated in two clinical trials in the United States and Europe.

HepaMate™ is an extracorporeal (outside the body), temporary liver support system designed to provide 'whole' liver function to patients with acute or severe liver failure. Unlike conventional technologies which use mechanical methods to perform rudimentary filtration of a patient's blood or partially detoxify blood by using albumin or sorbents, HepaMate™ combines the process of removing toxins from the patient's blood (detoxification) with concurrent biologic liver cell therapy.

During HepaMate™ therapy, the patient's plasma is first separated from whole blood, then exposed to the HepaMate™ bioartificial liver, and finally, returned to the patient. HepaMate™ is comprised of a blood plasma separation cartridge, a hollow-fiber bioreactor filled with proprietary porcine liver cells, a charcoal column, an oxygenator, and a plasma reservoir. These components are assembled into a patented blood/plasma circulation system, which is placed on our HepaDrive™ perfusion platform.

HepaMate™ is designed to provide whole liver function by using liver cells which are expected to remove toxins and produce albumin and other important liver-specific proteins. In order to easily and safely store and distribute our liver cells, we use a patented liver cell cryopreservation process which freezes the cells and allows for their prolonged storage. We believe our patented cryopreservation process provides us with a significant commercial and logistical advantage over technologies reliant upon the delivery of fresh cells which cannot typically be stored for prolonged periods and therefore, have shorter shelf-lifetimes than our cells used in HepaMate™.

HepaMate™, previously known as "'HepatAssist," has been clinically evaluated in a successful Phase I clinical trial. Following these results, a pivotal Phase II/III prospective, randomized, controlled trial in 171 patients (with fulminant/subfulminant hepatic failure and primary non-function following a failed liver transplant) was conducted in 11 U.S. and 9 European medical centers. The clinical data was published in 2004 and showed that, based on a retrospective analysis, liver failure patients with fulminant and sub-fulminant hepatic failure who were treated with the bioartificial liver achieved a significant survival advantage when compared against the patient control group

receiving standard-of-care treatment without bioartificial liver support.

We believe the inclusion of a subset of 24 patients who had undergone a prior, failed liver transplant negatively impacted the Phase II/III trial's outcome since such patients are known to have poor survival outcomes. As a consequence, the pivotal Phase II/III trial was unable to achieve its primary 30-day survival endpoint in the overall study population. Based on our retrospective statistical analysis of the clinical trial data, we anticipate, but cannot assure, that a new Phase III clinical trial without the inclusion of such failed liver transplant patients may be successful.

Table of Contents

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

Due to the pre-revenue, clinical development stage of our business, we expect to incur losses as we continue conducting our ongoing product development program. We will require additional funding to continue our product development program, to conduct a new clinical Phase III trial for HepaMate™, for operating expenses, to pursue regulatory approvals for our product, 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 currently do not have any arrangements or agreements with any third parties relating to such additional funding. 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 funding will be available in amounts and on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly our development program 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.

USDA Agricultural Research Service

In November 2007, we entered into an exclusive license agreement with the USDA, ARS for the use of patented PICM-19 liver cell lines in bioartificial liver devices and in-vitro toxicological testing platforms. In September 2008, we amended our license agreement to expand the field-of-use to allow for use of the PICM-19 cells as “in-vitro infection host systems” for viral and protozoan agents such as malaria. The license agreement gives us exclusive rights to the use of PICM-19 liver cell lines in artificial liver devices and in-vitro toxicological testing platforms patented by two issued and one pending patent. Under the terms of the license agreement, we paid USDA, ARS a one-time license execution fee and are obligated to pay certain maintenance fees, milestone payments and royalties on future sales, if any.

The exclusive license agreement for the PICM-19 liver cell line with the USDA, ARS for the use of patented liver cell lines in artificial liver devices and in-vitro toxicological testing platforms remains in force and effect; the license was recently expanded for the additional use of PICM-19 as in-vitro infection host system for viral and protozoan agents such as malaria. We are continuing to evaluate the further optimization of our PICM-19 liver stem cell line for potential use in a future generation of the HepaMate™ bioartificial liver system

While we are currently maintaining the license agreement for the PICM-19 liver cell line in effect, contemporaneously with our acquisition of the HepatAssist related assets, we, through our subsidiary, HepaLife Biosystems, Inc. (“HepaBio”), have notified the USDA, ARS that HepaBio has elected to terminate the Cooperative Research and Development Agreement (the “CRADA”) between us and the USDA, ARS effective November 30, 2008.

Michigan State University

In June 2006, we, through our subsidiary, Phoenix BioSystems, Inc. (“PBS”), entered into an exclusive worldwide license agreement with Michigan State University for the use of the patented PBS-1 chick cell lines for the development of new cell-culture based flu vaccines. In February 2008, PBS amended the license agreement to include use of the PBS-12SF chick cell line for the development of new cell-culture based flu vaccines. The license agreement granted us exclusive rights to five issued patents. Under the terms of the license agreement, we paid MSU a one-time

license execution fee and are obligated to pay royalties based on future sales, if any, subject to annual minimum payments. In January 2009, in order to more fully focus our resources on the development of the HepaMate™ and related technologies, we provided written notice to MSU to terminating the license agreement relating to the PBS-12SF chick cell line effective April 24, 2009.

Table of Contents

Our Strategy

Currently, we are focusing a significant portion of our financial resources on the continued development of HepaMate™ and related technologies. We believe that our bioartificial liver development program, due to our existing pivotal clinical trial data, is one of the most advanced development programs of its kind. We expect to conduct a new Phase III clinical trial as soon as possible, subject to the availability of required funding which we estimate will exceed our current working capital.

Although there is no assurance that we will be successful, if we succeed in our efforts to develop our bioartificial liver and in obtaining regulatory approval for commercialization following successful clinical phase III trials of HepaMate™, 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
- direct marketing and selling of our products.

Ultimately, our commercial success will depend on our ability and the ability of our partners, 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 as well as the efficacy of competing technologies.

Competition

The biotechnology industry is characterized by intense competition, rapid product development and technological change. A number of companies, research institutions and universities are working on technologies and products that may be similar and/or potentially competitive with our cell-based bioartificial liver. Non–cell-based techniques initially developed for other conditions, have been used to treat severe acute liver failure for more than a decade. Until now, no controlled, multicenter, large, randomized, prospective trials have been carried out using non-cell-based systems; therefore, their effect on survival remains unknown.

There can be no assurance that competitors will not succeed in developing alternative clinical therapies that are more effective than any that may ultimately be derived from our development efforts or that would render any such product obsolete and non-competitive.

We face competition from a number of companies, some of which are substantially larger than we are and have access to resources far greater than ours. Some companies enjoy numerous competitive advantages over us, including:

- greater brand 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.

The brief description of the products and technologies being developed or marketed by our competitors listed below have been taken from publicly available documents or reports filed by these companies with the United States Securities and Exchange Commission.

Competitors With Artificial Liver Device Technologies In Advanced Clinical Evaluation

- Arbios Systems, Inc. – developing a non-biologic liver filtration device (“SEPET”) based on selective hemofiltration
- Fresenius AG – developed a non-biologic liver filtration system (“PROMETHEUS”) based on a dialysis principle to remove water-soluble and albumin bound toxins from the blood

Table of Contents

- Gambro AB – developed a non-biologic liver filtration system ("MARS") based on a dialysis principle to remove water-soluble and albumin bound toxins from the blood

- Vital Therapies, Inc. – developing a bioartificial liver device ("ELAD") that uses a line of human liver cells cultivated from a hepatoblastoma, a type of liver tumor

We believe that in order for us to compete with such companies, both for the acquisition of rights to viable biotechnologies and the financial resources required to ultimately attempt to commercialize such technologies, it is important for us to establish and maintain "brand" name recognition. Accordingly, we have undertaken a program designed to establish "brand" name recognition within the investment and scientific communities; we intend to continue to develop and market our brand name pending commercialization.

Our Intended Markets

Liver failure and the Need for an Artificial Liver Device

Each year an estimated two million people die of liver disease. The World Health Organization estimates that over 650 million people worldwide are affected by some form of liver disease, including 30 million Americans. China has the world's largest population of Hepatitis B patients (approx. 120 million) with 500,000 people dying of the liver disease every year.

In the US alone, there are around 500,000 critical episodes of liver problems requiring hospitalization with 80,000 deaths annually. Liver transplantation is currently the only therapy proven to extend survival but the waiting list for liver transplants is extensive and many on the list will not receive an organ due to a dramatic shortage of donors or not being eligible.

In 2007, according to the United Network for Organ Sharing, there were nearly 17,000 individuals on the US waiting list for a liver transplant. Only 30% of those in need were transplanted. The average waiting time was more than 400 days. The same year, about 1,300 people died while waiting for a suitable donor with no medical option for saving their life available. For those patients with fulminant hepatic failure, a severe liver disease with 60-90% mortality, depending on the cause, only 10% received a transplant. Liver transplantation has a relatively high mortality of 30-40% at 5 -8years with 65% of the deaths occurring in the first 6 months. In addition, patients who have undergone transplantation must use lifelong immunosuppressive therapy.

The need for a bioartificial liver device able to remove toxins and improve survival results is more critical today than ever before. Limited treatment options, a low number of donor organs, the high price of transplants and follow up costs, a growing base of hepatitis, alcohol abuse, drug overdoses, liver cancer and other factors, all clearly indicate a strong need for a bioartificial liver device.

Liver Failure Treatment

For 30 years the medical world has tried to create a life-saving bioartificial liver device. Hepatocytes, or liver cells, are the key to a functioning bioartificial liver. However, the liver is a complex organ to functionally replicate: it takes in oxygen and nutrients, and returns metabolic byproducts to the plasma; it must regulate the balance of fluids, electrolytes, and glucoses. The liver synthesizes albumin, globulins, and heparin, and filters out ammonia and toxins.

Currently, the standard treatment for acute liver failure involves supportive care that focuses on bridging patients to either transplantation or spontaneous recovery. Orthotopic liver transplantation is the only current therapy shown to improve patient survival.

Several extracorporeal liver support systems have been used to treat acute liver failure, attempting to bridge patients to either recovery or to transplantation. These include cell-based and non–cell-based systems. In the absence of treatment alternatives, non–cell-based techniques (eg, high-volume plasma exchange and albumin dialysis) initially developed for other conditions, have been used to treat severe acute liver failure for more than a decade. However, the clinical effect on patient survival in severe acute liver failure was limited.

Table of Contents

Extracorporeal liver perfusion using whole human and pig livers rather than cells has been shown to effectively support patients with acute liver failure for several days, but it is impractical for wider use because of limited availability of human livers and lack of quality control and consistency for animal livers. As a result, several extracorporeal cell-based devices were developed. Early Phase I studies have been performed using whole blood or plasma perfusion through cartridges (mostly hollow-fiber bioreactors) containing either human hepatoblastoma (tumor) cells or freshly isolated porcine hepatocytes. While such devices appeared to be well tolerated by patients, the studies did not demonstrate a survival advantage over standard care in appropriately controlled settings.

The Market Segments

Assuming the results from our development efforts and anticipated clinical trials prove successful, and subject to receiving regulatory approvals, we believe that we will have the potential to address two important clinical needs and market segments:

Acute Liver Failure

Acute liver failure (ALF) can develop from several distinct disease processes that are associated with the rapid loss of liver function, including fulminant hepatic failure (FHF), subfulminant hepatic failure, and primary nonfunction of a transplanted liver. FHF is usually used as a generic term encompassing a range of definitions that are based on the time of onset of hepatic encephalopathy (coma).

FHF is the final common pathway for a variety of liver injuries. In FHF, the need for a liver replacement is urgent because of rapid deterioration in the patient's condition, often associated with irreversible brain damage.

In severe FHF, the mortality rate without liver transplantation approaches up to 90% and individuals diagnosed with FHF are placed at the top of the transplant waiting list (Status I). We anticipate that our HepaMate™ bioartificial liver may help keep patients alive and maintain their neurological state until their own liver potentially recovers and regenerates to normal function (bridge to recovery), or until a donor liver becomes available for transplantation to the patient (bridge to transplantation).

In FHF patients, we anticipate that our HepaMate™ bioartificial liver therapy will:

- Allow survival without a transplant (a bridge to liver regeneration)
- Reduce the risk of pre-transplant death
- Help keep liver failure patients alive and neurologically intact before, during and immediately after transplantation
- Improve survival in individuals with drug-induced liver toxicity
- Improve survival with drug-induced liver toxicity

Acute-on-Chronic and Chronic Liver Failure

These patients experience recurrent acute episodes of liver failure which are very difficult and costly to treat. The large majority of these patients do not become eligible for liver transplantation until very late in their disease course, if ever, by which time they may be contraindicated for such an invasive surgical procedure. Thus, we anticipate that the principal objective for use of our HepaMate™ bioartificial liver will be to bridge these patients to regeneration and recovery of their own liver. Over several years, we anticipate that such patients may be repeatedly treated with our HepaMate™ bioartificial liver in response to recurring, acute episodes.

For acute-on-chronic and chronic liver failure patients, we anticipate that potential indications for the HepaMate™ bioartificial liver may include its use in: (a) treatment of acute episodes (or flares) of chronic liver disease, or

acute-on-chronic liver failure arising from specific viral hepatitis strains; (b) prevention of acute-on-chronic episodes of liver failure; (c) treatment of acute alcoholic hepatitis, and; (d) use in conjunction with multi-drug anti-viral therapy in refractory viral hepatitis patients, where liver injury may impede immune response to conventional administration of antiviral drugs.

Marketing of Commercialized Products

We do not have any commercialized products, nor is there any assurance that we will have any such products; accordingly, we have no sales organization or agreements with third parties regarding the sale and marketing of any products which we may eventually commercialize. To the extent that we may 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 development efforts would be delayed or terminated.

Table of Contents

Our ability to achieve profitability is dependent in part on ultimately obtaining regulatory approvals for products, if any, which are derived from our development efforts, and then commercialize either through our own sales force or by entering into sales/marketing agreements for the commercialization of any such products with third parties or strategic partners. 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 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 ourselves, through distribution, co-marketing, co-promotion or sublicensing arrangements with third parties.

Employees

At December 31, 2008, we had one full-time employee. We do not have any part-time employees. Our employee is not represented by a labor union or other collective bargaining groups. We consider relations with our employee to be good. To the best of our knowledge, none of our employees, officers or directors are bound by restrictive covenants from prior employers which would preclude them from providing services to the Company. We currently plan to retain and utilize the services of outside consultants for additional research, testing, regulatory, accounting, legal compliance and other services on an as needed basis.

ITEM 2. PROPERTIES.

Our current corporate office is located at 60 State Street, Suite 700, Boston, MA 02109. Until August 30, 2008, our administrative office was located at 1628 West First Avenue, Suite 216, Vancouver, BC, Canada, V6J 1G1. A private corporation controlled by Mr. Harmel S. Rayat, a former secretary, treasurer, chief financial officer, chairman, director and majority stockholder, owns the Vancouver, BC premises.

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.

The Annual Meeting of Stockholders (the “Annual Meeting”) of the Company was held on October 15, 2008, at which time the stockholders voted on the following proposals:

1. The election of a board of directors to serve until the next Annual Meeting or until their respective successors are duly elected and have qualified.

	Votes For	Votes Against	Votes Abstaining
Frank Menzler	75,375,906	249,536	258,252
Harmel Rayat(1)	74,976,748	611,054	295,892
Javier Jimenez	75,376,206	242,860	264,630
Roland Schomer	75,414,859	206,215	262,622

(1) Mr. Rayat had resigned on September 12, 2008 and did not stand for re-election even though his name was on the ballot.

Table of Contents

2. Ratifying the appointment of Peterson Sullivan LLP as our auditors for the fiscal year ending December 31, 2008.

Votes For	Votes Against	Votes Abstained
75,459,046	202,467	222,185

In addition, shareholders (the "Consenting Stockholders") owning an aggregate of 48,196,884 shares of our Common Stock constituting approximately 52% of the voting stock of the Company executed and delivered to us a written consent effective October 15, 2008 electing each of Jatinder S.Bhogal and Joseph Sierchio to our Board of Directors.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

The Company's Common Stock is listed on the OTC Bulletin Board under the symbol "HPLF." We are engaged in a highly dynamic industry, which often results in significant volatility of our common stock price.

The following table sets forth the high and low sale prices for the periods indicated:

	High	Low
First Quarter 2007	$ 0.70	$ 0.41
Second Quarter 2007	$ 1.76	$ 0.55
Third Quarter 2007	$ 1.07	$ 0.57
Fourth Quarter 2007	$ 0.85	$ 0.36
First Quarter 2008	$ 0.47	$ 0.31
Second Quarter 2008	$ 0.73	$ 0.45
Third Quarter 2008	$ 0.48	$ 0.18
Fourth Quarter 2008	$ 0.31	$ 0.14
January 1, 2009 – March 20, 2009	$ 0.27	$ 0.15

On March 20, 2009, the closing price of a share of our common stock as reported on the OTCBB was $0.22. As of March 20, 2009, there were approximately 69 stockholders of record of the Company's Common Stock.

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 to be issued upon exercise of	Weighted-average exercise price of outstanding	Number of securities remaining available for future issuance under equity compensation plans

Plan Category	outstanding options, warrants and rights (a)	options, warrants and rights (b)	(excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,700,000	$ 0.53	35,098,000
Equity compensation plans not approved by security holders			
Total	2,700,000	$ 0.53	35,098,800

12

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

Discussion and Analysis

The following discussion and analysis is based upon our consolidated 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 "Forward Looking Statements," and elsewhere in this Form 10-K.

Overview

We are a development stage biotechnology company focusing on the development of a cell-based bioartficial liver system, HepaMate(TM), as a potentially lifesaving treatment for liver failure patients. The technology has previously been successfully tested in a clinical phase I study. As an extracorporeal cell-based bioartificial liver system, HepaMate(TM) is designed to combine blood detoxification with liver cell therapy to provide whole liver function in patients with the most severe forms of liver failure.

On October 3, 2008, in order to enhance and strengthen our pre-existing bioartificial liver development program, we acquired HepaAssist Related Assets from Arbios Systems, Inc. ("Arbios"), which assets included over 12 patents and patent licenses; miscellaneous scientific equipment; FDA Investigative New Drug (IND) application, including orphan drug and fast track designation; Phase I and Phase II/III clinical protocols and clinical data; and standard operating procedures for manufacturing and quality control. The acquired assets relate to a bioartificial liver device formerly known as "HepatAssist." HepatAssist passed clinical Phase I studies was evaluated in the largest-ever Phase II/III clinical study (prospective, randomized, multicenter, controlled trial involving over 170 patients) to test the safety and efficacy of a bioartificial liver assist device. The clinical data was published in 2004 and showed for bioartificial liver device treated patients in fulminant and sub-fulminant hepatic failure a significant survival advantage compared with the patient control group receiving standard-of-care treatment.

We are working towards optimizing the former HepatAssist bioartificial liver device for utilization in a new, successful clinical Phase II/III study followed by commercialization upon final regulatory approval.

Previously we focused our research, development and commercialization efforts on the development of a porcine stem cell line, and subclones thereof, which we refer to as the "PICM-19 cell line" for use in a bioartificial liver and in-vitro toxicology testing, and on the commercialization of a chicken cell line, and subclones thereof, which we refer to as the "PBS-1 cell line." The PBS-1 cell line was developed for potential use in cell-based vaccine production and was exclusively licensed from Michigan State University in June 2006.

The PICM-19 cell line was developed for potential use in a bioartificial liver device and in-vitro toxicology platforms and was exclusively licensed from USDA Agricultural Research Service on November 2007. In September 2008 the license was amended for the expanded field-of-use as in-vitro infection host systems for viral and protozoan agents such as malaria.

On May 23, 2008, we completed a private placement of securities for an aggregate purchase price of $4,530,800. Simultaneously with the completion of the private placement, we converted our outstanding note payable of $877,800 into equity and the note holder agreed to accept $150,000 in full payment and satisfaction of the accrued and unpaid interest on the loan in the amount of $249,945.

Asset Purchase Agreement

On October 3, 2008, the Company entered into and consummated the transactions contemplated by a purchase agreement with Arbios. Pursuant to the purchase agreement, the Company, in order to enhance and strengthen its current PICM-19 porcine liver cell line based bioartifical liver technology, purchased certain specified assets of Arbios relating to the pig cell based liver device technology that was being developed by Arbios.

Table of Contents

The purchase price of the acquired assets consisted of: $450,000 in cash, of which $250,000 was paid at the closing and $200,000 has been deferred for up to 18 months; a Series D Stock Purchase Warrant to purchase up to 750,000 shares of the Company's common stock at an exercise price of $0.35 per share for a period of 5 years. The deferred $200,000 payment is due and payable on the earlier of (i) the date on which we consummate one or more debt or equity financings in which the gross proceeds received in the aggregate equal or exceed $4,000,000, or (ii) the eighteen month anniversary of the closing date.

The issuance of the Series D Warrant was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act in that the issuance did not involve a public offering. We granted Arbios certain registration rights, as more fully set forth in the Registration Rights Agreement dated October 3, 2008 between the Company and Arbios, with respect to the shares of the Company's common stock issuable upon exercise of the Series D warrant. Pursuant to the Registration Rights Agreement, if we have not filed with, and have declared effective by, the Securities and Exchange Commission, a registration statement within nine months of October 3, 2008, Arbios, to the extent applicable, will be entitled to utilize the cashless exercise provisions of the Series D Warrant.

May 2008 Private Placement

On May 23, 2008, we completed a private placement (May 2008 Private Placement) pursuant to which we sold 10,660,705 units (Units) at a price of $0.425 per Unit or $4,530,800 in the aggregate. Each Unit consists of one share of the Company's common stock (the "Unit Shares") and one Series C stock purchase warrant (Series C warrant) to purchase a share of common stock at the initial exercise price of $0.55 per share for a period of two years from the date of issuance. In conjunction with our completion of the acquisition of the HepatAssist related assets in October 2008, we reduced the initial exercise price of the Series C warrants to $0.34 per share. We also issued an additional 263,713 Units in payment of placement and legal fees relating to this transaction. We have agreed to register for resale the Unit Shares and the shares of our common stock issuable upon exercise of our common stock.

Loan Conversion

Simultaneously with the completion of the May 2008 Private Placement, we entered into an agreement with Mr. Harmel S. Rayat, the Company's former Chief Financial Officer, Director and Controlling Shareholder, pursuant to which Mr. Rayat (i) converted the entire outstanding principal amount ($877,800) of his loan to the Company into an aggregate of 2,065,412 Units, each Unit consisting of one share of the Company's common stock and one Series C warrant, at a conversion price of $0.425 per Unit and (ii) agreed to accept $150,000 in full payment and satisfaction of the accrued and unpaid interest on the loan in the amount of $249,945.

Warrants

As of December 31, 2008, the following warrants were outstanding: 12,989,830 Series C warrants with an exercise price of $0.34 per share exercisable into common stock until May 23, 2010; 750,000 Series D warrants with an exercise price of $0.35 per share exercisable into common stock until October 3, 2013; and 737,000 warrants with an exercise price of $1.50 per share exercisable into common stock until May 11, 2012.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated 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:

Table of Contents

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology, as well as purchased in-process research and development programs. Until October 2008, the majority of costs incurred were pursuant to our CRADA with the USDA's Agricultural Research Service and pursuant to our sponsored research agreement with MSU. Third-party costs paid by us relating to these agreements include salaries and benefits for research and development personnel, allocated overhead and facility occupancy costs, contract services and other applicable costs. In addition, costs may include third party laboratory work. We charge all research and development expenses to operations as they are incurred, including internal costs, costs paid to sponsoring organizations, and purchased in-process research and development programs. We do not track research and development expenses by project.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel related costs, legal costs, including intellectual property that is expensed when incurred, investor relations costs, stock based compensation costs, accounting costs, and other professional and administrative costs.

Stock-Based Compensation Expense

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," (SFAS 123R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. Our consolidated financial statements reflect the impact of SFAS 123(R) from the date of adoption.

Results of Operations

We have yet to establish any history of profitable operations and our accumulated deficit from inception through December 31, 2008 is $19.3 million. We have not generated any revenues from operations during the past five years and do not expect to generate any revenues for the foreseeable future. We expect that our future revenues will not be sufficient to sustain our operations for the foreseeable future. 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.

We expect to continue to incur losses from business operations and we believe our cash and cash equivalents balances, anticipated cash flows from operations, and other external sources of credit will be sufficient to meet our cash requirements through March 2010. The future of the Company after March 2010 will depend in large part on our ability to successfully raise capital from external sources to pay for planned expenditures and to fund operations.

Results of Operations for Years Ended December 31, 2008 and 2007

We had no revenues in 2008 and 2007.

Operating expenses were $2,961,820 for the year ended December 31, 2008, an increase of $280,707 or 10.5%, from $2,681,113 during the same period in 2007. The increase was due to the following: a $719,853 or 417.2% increase in research and development costs primarily relating to the effective purchase price of $548,325 of in-process research and development, as well as an increase in costs resulting from the renegotiation of the CRADA agreement in November 2007; and an increase in legal and accounting expenses of $104,529 or 104.6% due to increased activity. These increases were offset by a net decrease of $355,737 or 23.5% in salaries and benefits cost due to the closing of

the administration office in Canada and the refocus of our technology efforts resulting in the termination of certain employees, as well as a $191,120 or 35.4% decrease in investor relations expenses. Shareholder and investor relations expenses include a $170,000 charge that was settled by issuing 400,000 common stock shares at an effective price of $0.425 per share.

Table of Contents

Interest income decreased 21.8% to $30,831 in 2008 from $39,451 in 2007 resulting from a substantially lower interest rate environment during 2008. The net of interest expense and amortization of both debt discount and deferred financing costs decreased $1,063,039 or 59.2% from $1,796,535 to $733,496 due to the conversion of debt to equity during 2007 with the remainder in 2008.

We recorded a loss on disposal of fixed assets of $3,061 in 2008 as a result of removing the cost and related accumulated depreciation of equipment that was either no longer in service or deemed obsolete. Substantially all of this equipment was located at the Company's administrative office in Vancouver, British Columbia, Canada, which, effective September 1, 2008, was closed.

Our net loss to common stockholders for 2008 decreased 17.4% to $3,667,547 from $4,438,197 in 2007. On a basic and diluted per share basis, the net loss to common stockholders improved from $0.06 per share net loss in 2007 to $0.04 per share net loss in 2008. As of December 31, 2008, we have an accumulated deficit of $19,321,616. We may incur substantial operating losses in future periods.

Liquidity and Capital Resources

We had cash and cash equivalents of $3,084,155 and $534,113 as of December 31, 2008 and, 2007, respectively. Net cash provided by financing activities was $4,530,800 for the year ended December 31, 2008 from a private placement of securities of 10,660,705 units, with each unit consisting of one share of common stock and one common stock warrant. For the year ended December 31, 2007, net cash provided by financing activities was $2,259,276 from the purchase of 891,019 shares of common stock by Fusion Capital for total proceeds of $495,001 and proceeds of $2,125,000 from the issuance of convertible notes (which have been converted to equity in their entirety as of December 31, 2008), offset by $132,200 repayment of promissory notes and $228,525 amortization of deferred financing costs.

Net cash flow used in operating activities was $1,984,149 for the year ended December 31, 2008, compared to net cash flow used of $1,895,400 for the same period in 2007. We have financed operations primarily from cash on hand and through private placements of securities, as well as through the issuance of convertible debt. The accompanying financial statements have been prepared assuming we will continue as a going concern. We incurred cumulative losses of $19,321,616 from inception through December 31, 2008. Additionally, we have expended a significant amount of cash in developing our technology. We expect to continue to incur losses from business operations and we believe our cash and cash equivalents balances, anticipated cash flows from operations, and other external sources of credit will be sufficient to meet our cash requirements through March 2010. The future of the Company after March 2010 will depend in large part on our ability to successfully raise capital from external sources to pay for planned expenditures and to fund operations.

At this time, we have no agreements or understandings with any third party regarding any financings.

Related Party Transactions

Director and Management Fees: For the year ended December 31, 2008, we incurred $19,343 in board fees for non-employee directors of the Company. In addition, during June and September 2008, we granted stock options to purchase 50,000 shares each for a total of 200,000 shares of common stock to non-employee board members. For the year ended December 31, 2008, we recorded $12,541 as stock compensation expense relating to these stock grants. During the year ended December 31, 2007, we paid management fees of $4,900 to the directors. There is no management or consulting agreements in effect.

Legal Fees: In relation to our May 2008 Private Placement, we settled $21,250 in legal costs by issuing 50,000 Units to our attorney who also serves as a board member. Legal fees expensed for the year ended December 31, 2008 that were paid or were due to this attorney total $111,150.

Notes Payable and Accrued Interest: On May 23, 2008, we reached an agreement with Mr. Harmel Rayat pursuant to which Mr. Rayat (i) converted the entire outstanding principal amount ($877,800) of his loan to the Company into an aggregate of 2,065,412 Units, each Unit consisting of one share of the Company's common stock and one Series C warrant, at a conversion price of $0.425 per Unit and (ii) agreed to accept $150,000 in full payment and satisfaction of the accrued and unpaid interest on the loan in the amount of $249,945.

Table of Contents

Rent: Until August 31, 2008, our administrative office was located at 1628 West 1st Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. This premise is owned by a private corporation controlled by Mr. Rayat. We paid rent of $26,866 for the year ended December 31, 2008 (2007: $35,740). Effective September 1, 2008, we closed this administrative office, terminating all of our employees at this location. There were no severance arrangements with any of the terminated employees.

Mr. Harmel S. Rayat was an officer and director of the Company until September 12, 2008 and a majority stockholder of the Company until September 9, 2008. All related party transactions are recorded at the exchange amount established and agreed to between related parties and are in the normal course of business.

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements in this Form 10-K.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Index to Financial Statements

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
HepaLife Technologies, Inc.
Boston, Massachusetts

We have audited the accompanying consolidated balance sheets of HepaLife Technologies, Inc. and Subsidiaries (a development stage company) ("the Company") as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and for the period from October 21, 1997 (date of inception) to December 31, 2008. 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 audits.

We conducted our audits 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. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of HepaLife Technologies, Inc. and Subsidiaries (a development stage company) as of December 31, 2008 and 2007, and the results of their operations and their cash flows for the years then ended, and for the period from October 21, 1997 (date of inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States.

/S/ PETERSON SULLIVAN LLP

March 20, 2009
Seattle, Washington

Table of Contents

HEPALIFE TECHNOLOGIES, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
December 31, 2008 and 2007

(Expressed in U.S. Dollars)	2008	2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,084,155	$ 534,113
Prepaid expenses (Note 7)	98,716	4,338
Total current assets	3,182,871	538,451
Equipment, net (Note 6)	-	10,882
License fee	-	75,000
Deferred financing costs (Note 8)	-	210,728
Total assets	$ 3,182,871	$ 835,061
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	$ 105,250	$ 4,800
Accounts payable - related parties (Note 5)	-	208,330
Notes payable - related party (Note 5)	-	877,800
Total current liabilities	105,250	1,090,930
Contract commitment payable (Note 4)	200,000	-
Discount on contract commitment payable	(12,873)	-
Convertible promissory note, at face value (Note 8)	-	755,000
Discount on convertible promissory notes	-	(468,343)
	187,127	286,657
Total liabilities	292,377	1,377,587
STOCKHOLDERS' EQUITY (DEFICIT)		
Stockholders' equity (deficit) (Note 9)		
Preferred stock: $0.10 par value; Authorized: 1,000,000 Issued and outstanding: none	-	-
Common stock: $0.001 par value; Authorized: 300,000,000Issued and outstanding: 91,996,829 (2007: 76,264,584)	91,998	76,265
Additional paid-in capital	22,120,493	15,039,050
Accumulated other comprehensive income	(381)	(3,772)
Loss accumulated during the development stage	(19,321,616)	(15,654,069)
Total stockholders' equity (deficit)	2,890,494	(542,526)
Total liabilities and stockholders' equity	$ 3,182,871	$ 835,061

(The accompanying notes are an integral part of these financial statements)

Table of Contents

HEPALIFE TECHNOLOGIES, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2008 and 2007
and from inception (October 21, 1997) to December 31, 2008

(Expressed in U.S. Dollars)	2008	2007	From inception (October 21, 1997) to December 31, 2008
Revenue	$ -	$ -	$ -
Expenses			
Salary and benefits	1,157,785	1,513,522	5,634,755
Research and development (Notes 4 and 7)	892,386	172,533	1,913,674
Shareholder and investor relations	354,308	544,943	4,154,714
Administrative and general	324,393	307,035	1,259,340
Professional fees- accounting and legal	204,422	99,893	711,943
Director, management and consulting fees (Note 5)	20,705	26,932	1,023,042
Depreciation	7,821	16,255	35,410
Stock offering costs	-	-	1,926,713
	2,961,820	2,681,113	16,659,591
Operating Loss	(2,961,820)	(2,681,113)	(16,659,591)
Other income and expenses			
Interest on promissory note (Note 5)	(41,615)	(80,431)	(355,112)
Interest, bank charges and foreign exchange loss	(11,261)	(8,561)	(35,807)
Interest income	30,831	39,451	120,119
Loss on disposal of fixed assets	(3,061)	-	(3,061)
Amortization of discount on convertible notes (Note 8)	(469,893)	(1,624,756)	(2,094,649)
Amortization of deferred financing costs (Note 8)	(210,728)	(82,787)	(293,515)
	(705,727)	(1,757,084)	(2,662,025)
Net loss available to common stockholders	$ (3,667,547)	$ (4,438,197)	$ (19,321,616)
Loss per share - basic and diluted	$ (0.04)	$ (0.06)	
Weighted average number of common shares outstanding - basic and diluted	85,952,917	74,101,897	

(The accompanying notes are an integral part of these financial statements)

Table of Contents

HEPALIFE TECHNOLOGIES, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
from inception (October 21, 1997) to December 31, 2008

(Expressed in U.S. Dollars)	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Accumulated other comprehensive income	Loss accumulated during development stage	Comprehensive income (loss)	Total stockholders' equity (deficit)
Common stock issued for service 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	42
Total comprehensive income						42	
Balance, December 31, 1997	13,200,000	13,200	64,800	-	42	-	78,042
Common stock issued for service rendered at $0.025 per share, December 15, 1998	16,000,000	16,000	384,000	-	-	-	400,000

Comprehensive income (loss) Loss, year ended December 31, 1998	-	-	-	-	(471,988)	(471,988)	(471,988)
Total comprehensive income						(471,988)	
Balance, December 31, 1998	29,200,000	29,200	448,800	-	(471,946)		6,054
Common stock issued for cash at $0.025 per share, March 1999	12,000,000	12,000	288,000	-	-	-	300,000
Comprehensive income (loss) Loss, year ended December 31, 1999	-	-	-	-	(121,045)	(121,045)	(121,045)
Total comprehensive income						(121,045)	
Balance, December 31, 1999	41,200,000	41,200	736,800	-	(592,991)	-	185,009
Comprehensive income (loss) Loss, year ended December 31, 2000	-	-	-	-	(80,608)	(80,608)	(80,608)
Total comprehensive income						(80,608)	
Balance, December 31, 2000	41,200,000	41,200	736,800	-	(673,599)		104,401
Conversion of debt to equity at $0.015 per share,	8,933,332	8,933	125,067	-	-	-	134,000

July 31, 2001							
Comprehensive income (loss) Loss, year ended December 31, 2001	-	-	-	-	(160,364)	(160,364)	(160,364)
Total comprehensive income						(160,364)	
Balance, December 31, 2001	50,133,332	50,133	861,867	-	(833,963)	-	78,037
Common stock issued for services at $0.06 per share, April 23, 2002	10,000	10	590	-	-	-	600
Conversion of debt to equity at $0.05 per share, April 26, 2002	2,160,000	2,160	105,840	-	-	-	108,000
Common stock issued for investor relations services at $0.05 per share, July 25, 2002	2,390,000	2,390	117,110	-	-	-	119,500
Conversion of debt to equity at $0.05 per share, December 18, 2002	1,920,000	1,920	94,080	-	-	-	96,000
Comprehensive income (loss) Loss, year ended December 31, 2002	-	-	-	-	(375,472)	(375,472)	(375,472)
Total comprehensive income						(375,472)	
	56,613,332	56,613	1,179,487	-	(1,209,435)		26,665

Balance, December 31, 2002							
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)	(1,102,723)
Total comprehensive income						(1,102,723)	
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 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	2,000,000	2,000	48,000	-	-	-	50,000

share							
Comprehensive income (loss) Loss, year ended December 31, 2004	-	-	-	-	(1,435,613)	(1,435,613)	(1,435,613)
Total comprehensive income						(1,435,613)	
Balance, December 31, 2004	67,817,832	67,818	3,141,002	-	(3,747,771)	-	(538,951)
Common stock issued pursuant to exercise of stock options in March 2005 at $3.10 per share	50,000	50	154,950	-	-	-	155,000
Common stock issued pursuant to exercise of stock options in May 2005 at $2.11 per share	45,000	45	94,905	-	-	-	94,950
Common stock issued pursuant to exercise of stock options in June 2005 at $2.11 per share	100,000	100	210,900	-	-	-	211,000
Common stock issued pursuant to exercise of stock options in October 2005 at $2.11 per share	40,000	40	84,360	-	-	-	84,400
Common stock issued pursuant to exercise of stock options in March 2005 at $2.11 per share	50,000	50	105,450	-	-	-	105,500

Common stock issued pursuant to exercise of share purchase warrants in March 2005 at $0.025 per share	1,250,000	1,250	30,000	-	-	-	31,250
Restricted common stock issued in June 2005 pursuant to share purchase agreement	20,000	20	37,580	-	-	-	37,600
Restricted common stock issued in July 2005 pursuant to share purchase agreement	691,598	692	1,382,504	-	-	-	1,383,196
Comprehensive income (loss) Loss, year ended December 31, 2005	-	-	-	-	(2,813,602)	(2,813,602)	(2,813,602)
Total comprehensive income						(2,813,602)	
Balance, December 31, 2005	70,064,430	70,065	5,241,651	-	(6,561,373)	-	(1,249,657)
Restricted common stock issued in January 2006 pursuant to share purchase agreement	374,753	375	505,542	-	-	-	505,917
Common stock issued in the first quarter of 2006 to Fusion Capital for cash	431,381	431	449,569	-	-	-	450,000
Common stock issued in the	416,303	416	329,584	-	-	-	330,000

second quarter of 2006 to Fusion Capital for cash							
Common stock issued in the third quarter of 2006 to Fusion Capital for cash	758,606	759	584,234	-	-	-	584,993
Common stock issued in the fourth quarter of 2006 to Fusion Capital for cash	548,371	548	354,455	-	-	-	355,003
Exercise of stock options	175,000	175	12,075	-	-	-	12,250
Stock based compensation expenses	-	-	2,607,302	-	-	-	2,607,302
Comprehensive income (loss) Loss, year ended December 31, 2006	-	-	-	-	(4,654,499)	(4,654,499)	(4,654,499)
Total comprehensive income						(4,654,499)	
Balance, December 31, 2006	72,768,844	72,769	10,084,412	-	(11,215,872)		(1,058,691)
Common stock issued in the first quarter of 2007 to Fusion Capital for cash	382,000	382	204,619	-	-	-	205,001
Common stock issued in the second quarter of 2007 to Fusion Capital for cash	509,019	509	289,491	-	-	-	290,000
Common stock converted from	2,604,721	2,605	1,742,395	-	-	-	1,745,000

convertible promissory notes							
Stock based compensation expenses	-	-	935,044	-	-	-	935,044
Proceeds allocated to the warrants issued with the convertible notes	-	-	497,689	-	-	-	497,689
Warrants issued for the payment of broker's fees	-	-	64,990	-	-	-	64,990
Intrinsic value of the beneficial conversion feature of the notes	-	-	1,220,410	-	-	-	1,220,410
Comprehensive income (loss) Foreign currency translation adjustment	-	-	-	(3,772)	-	(3,772)	(3,772)
Loss, year ended December 31, 2007	-	-	-	-	(4,438,197)	(4,438,197)	(4,438,197)
Total comprehensive income						(4,441,969)	
Balance, December 31, 2007	76,264,584	76,265	15,039,050	(3,772)	(15,654,069)		(542,526)
Common stock converted from convertible promissory notes in January 2008	2,342,415	2,343	752,657	-	-	-	755,000
Common stock converted from notes in June 2008	2,065,412	2,065	975,680	-	-	-	977,745

Common stock and warrants issued for cash, at $0.425 per share in May 2008 andin payment of placement and legal fees	10,924,418	10,925	4,519,875	-	-	-	4,530,800
Common stock issued for services received in 2008	400,000	400	169,600	-	-	-	170,000
Warrants granted for purchase of in-process research and development in October 2008	-	-	98,325	-	-	-	98,325
Stock based compensation expenses	-	-	565,306	-	-	-	565,306
Comprehensive income (loss) Foreign currency translation adjustment	-	-	-	3,391	-	3,391	3,391
Loss, year ended December 31, 2008	-	-	-	-	(3,667,547)	(3,667,547)	(3,667,547)
Total comprehensive income						$ (3,664,156)	
Balance, December 31, 2008	91,996,829	$ 91,998	$ 22,120,493	$ (381)	$ (19,321,616)		$ 2,890,494

(The accompanying notes are an integral part of these financial statements)

Table of Contents

HEPALIFE TECHNOLOGIES, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
for the years ended December 31, 2008 and 2007
and from inception (October 21, 1997) to December 31, 2008

(Expressed in U.S. Dollars)	2008	2007	From inception (October 21, 1997) to December 31, 2008
Cash flows from operating activities:			
Net Loss	$ (3,667,547)	$ (4,438,197)	$ (19,321,616)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation	7,821	16,255	35,410
Amortization of license fees	87,500	-	87,500
Services paid by issuance of common stock	170,000	-	1,031,100
Stock offering costs paid by issuance of common stock	-	-	1,926,713
In-process research and development partially purchased by issuance of common stock warrants and a contract commitment payable, net of discount	283,903	-	283,903
Stock based compensation expenses	565,306	935,044	4,107,652
Amortization of discount on convertible promissory notes and contract commitment payable	469,893	1,624,756	2,094,649
Amortization of deferred financing costs	210,728	82,787	293,515
Loss on disposal of assets	3,061	-	3,061
Change in assets and liabilities:			
Decrease (increase) in prepaid expenses	(106,880)	(563)	(111,218)
Increase (decrease) in accounts payable	100,450	(165,277)	105,250
Increase (decrease) in accounts payable - related party	(108,384)	49,795	99,946
Net cash used in operating activities	(1,984,149)	(1,895,400)	(9,364,135)
Cash flows from investing activities:			
Purchase of property and equipment	-	(3,878)	(38,471)
Purchase of license fees	-	(75,000)	(75,000)
Net cash used in investing activities	-	(78,878)	(113,471)
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net	4,530,800	495,001	9,787,867
Proceeds from issuance of convertible notes	-	2,125,000	2,125,000
Net proceeds from (repayment of) promissory notes	-	(132,200)	877,800
Increase in deferred financing cost	-	(228,525)	(228,525)
Net cash provided by financing activities	4,530,800	2,259,276	12,562,142
Increase in cash and cash equivalents	2,546,651	284,998	3,084,536
Effect of foreign exchange rate	3,391	(3,772)	(381)
Cash and cash equivalents, beginning of period	534,113	252,887	-
Cash and cash equivalents, end of period	$ 3,084,155	$ 534,113	$ 3,084,155
Supplemental disclosure of cash flow information:			
Interest paid in cash	$ 150,000	$ 25,930	$ 247,575

Income tax paid in cash	$ -	$ -	$ -
Non-cash Investing and Financing Activities:			
Common stock and warrants issued for professional services	$ 282,078	$ -	$ 1,143,078
Issuance of common stock as stock offering costs	$ -	$ -	$ 1,926,713
Issuance of warrants for deferred financing costs	$ -	$ 64,990	$ 64,990
Conversion of note payable and related interest to equity	$ 977,745	$ -	$ 977,745
Conversion of debt to equity	$ 755,000	$ 1,745,000	$ 2,500,000

(The accompanying notes are an integral part of these financial statements)

Table of Contents

HEPALIFE TECHNOLOGIES, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008
(Expressed in U.S. Dollars)

NOTE 1 - BASIS OF PRESENTATION, GOING CONCERN UNCERTAINITIES

We are a development stage biotechnology company focusing on the development of a cell-based bioartificial liver system.

We have incurred net operating losses since inception. We face all the risks common to companies in early stages of development, including undercapitalization and uncertainty of funding sources, high initial expenditure levels, uncertain revenue streams, and difficulties in managing growth. We expect to continue to incur losses from business operations and we believe our cash and cash equivalents balances, anticipated cash flows from operations, and other external sources of credit will be sufficient to meet our cash requirements through March 2010. The future of the Company after March 2010 will depend in large part on our ability to successfully raise capital from external sources to pay for planned expenditures and to fund operations.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States, and include the accounts of HepaLife Technologies, Inc. and its subsidiaries, Phoenix BioSystems, Inc., HepaLife Technologies Ltd. and HepaLife Biosystems, Inc. Phoenix BioSystems, Inc. was incorporated under the laws of the State of Nevada on June 6, 2006. HepaLife Technologies Ltd. was incorporated on April 11, 2007 in British Columbia, Canada, for the purpose of streamlining business operations in Canada. HepaLife Biosystems, Inc. was incorporated in State of Nevada on April 17, 2007 for the purpose of categorizing operations and accounting associated with the Company’s research and development efforts with its patented PICM-19 cell line, artificial liver technologies, and in vitro toxicology testing systems. All significant inter-company transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 us. Actual results could differ from those estimates.

Reclassification

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

Cash and Cash Equivalents

We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. We did not have any cash equivalents at December 31, 2008 and 2007. We periodically have cash deposits in excess of insured limits.

Table of Contents

Equipment and Depreciation

Equipment is initially recorded at cost and is depreciated under the straight-line method over their estimated useful life as follows:

Computer equipment - 2 years
Furniture and fixtures - 2 years

Repairs and maintenance expenses are charged to operations as incurred.

Research and Development

Research and development costs are expensed as incurred and include purchased in-process research and development programs.

Income Taxes

We account for income taxes under the provisions of Statement of Financial Accounting Standard (or "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.

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 anti-dilutive.

Stock-Based Compensation

We account for stock-based compensation under SFAS No. 123(R) “Share-Based Payment,” which requires measurement of compensation cost for all stock-based awards at fair value on the date of grant and recognition of compensation over the service period for awards expected to vest. The fair value of stock options is determined using the Black-Scholes valuation model.

Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income" establishes standards for reporting and display of comprehensive income, its components and accumulated balances. We disclose required information on the Consolidated Statements of Stockholders' Equity (Deficit). Comprehensive income comprises equity changes except those resulting from investments by owners and distributions to owners.

Foreign Currency Translation

We maintain 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:

Table of Contents

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.

Intangible Assets

SFAS No. 142, “Goodwill and Other Intangible Assets” 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. No impairment of intangible assets was recorded during the years ended December 31, 2008 and 2007.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment when changes in circumstances indicate their carrying value has become impaired, pursuant to guidance established in SFAS No 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” We consider 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.

Fair Value of Financial Instruments

The determination of 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 judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair values. The carrying value of cash and accounts payable, accrued liabilities and notes payable approximates their fair value because of the short-term nature of these instruments. We place our cash with high credit quality financial institutions.

Related Party Transactions

A related party is generally defined as (i) any person who holds 10% or more of the Company’s securities and their immediate families, (ii) the Company’s management, (iii) someone who 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 5).

Recent and Adopted Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, “Fair Value Measurements” (SFAS 157), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair-value measurements required under other accounting pronouncements. It does not change existing guidance as to whether or not an instrument is carried at fair value. SFAS 157 was effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-1 (FSP FAS 157-1), which excludes SFAS

No. 13, “Accounting for Leases” and certain other accounting pronouncements that address fair value measurements under SFAS 13, from the scope of SFAS 157. In February 2008, the FASB issued FSP No. 157-2 (FSP FAS 157-2), which provides a one-year delayed application of SFAS 157 for nonfinancial assets and liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Therefore we have adopted the provisions of SFAS 157 with respect to financial assets and liabilities only. We are required to adopt SFAS 157 as amended by FSP FAS 157-1 and FSP FAS 157-2 on January 1, 2009, the beginning of our fiscal year, as related to nonfinancial assets and liabilities. We do not expect the application of the amended aspects of SFAS No. 157 to have a material effect on the Company’s consolidated financial statements.

Table of Contents

In October 2008, the FASB issued FASB Staff Position No. FAS 157-3, "Determining the Fair Value of a Financial Asset in a Market That Is Not Active" (FSP FAS 157-3), which clarifies the application of SFAS 157 when the market for a financial asset is inactive. Specifically, FSP FAS 157-3 clarifies how (1) management's internal assumptions should be considered in measuring fair value when observable data are not present, (2) observable market information from an inactive market should be taken into account, and (3) the use of broker quotes or pricing services should be considered in assessing the relevance of observable and unobservable data to measure fair value. The guidance in FSP FAS 157-3 is effective immediately and did not have an impact on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-Including an amendment of FASB Statement No. 115," which is effective for fiscal years beginning after November 15, 2007. The statement permits entities to choose to measure many financial instruments and certain other items at fair value. The Company has not elected the fair value option under SFAS 159 for any instrument, but may elect to do so in future periods.

In July 2007, the Emerging Issues Task Force (EITF) issued EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities" (EITF 07-3). EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The Company's adoption of EITF 07-3 did not have an impact on the Company's financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an Amendment of Accounting Research Bulletin No 51" (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, changes in a parent's ownership of a noncontrolling interest, calculation and disclosure of the consolidated net income attributable to the parent and the noncontrolling interest, changes in a parent's ownership interest while the parent retains its controlling financial interest and fair value measurement of any retained noncontrolling equity investment. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company must adopt SFAS 160 on January 1, 2009, the beginning of its fiscal year 2009. The Company does not expect the application of SFAS 160 to have a material effect on the consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, "Business Combinations" (SFAS 141R), which establishes principles and requirements for the reporting entity in a business combination, including recognition and measurement in the financial statements of the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. The Company must adopt SFAS 141R on January 1, 2009, the beginning of its fiscal year 2009. For any business combinations entered into by the Company subsequent to January 1, 2009, the Company will be required to apply the guidance in SFAS 141R.

In December 2007, the FASB ratified a consensus opinion reached by the EITF on EITF Issue 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). The guidance in EITF 07-1 defines collaborative arrangements and establishes presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement). The consensus in EITF 07-1 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. The consensus requires retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective

application is impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. The Company intends to adopt EITF 07-1 effective January 1, 2009 and retrospectively apply the requirements of this consensus to its collaborative arrangements in existence on that date, if any. The Company currently does not believe that the adoption of EITF 07-1 will have a significant effect on its financial statements.

In December 2007, the SEC staff issued Staff Accounting Bulletin (SAB) 110, “Share-Based Payment” (SAB 110) which amends SAB 107, “Share-Based Payment,” to permit public companies, under certain circumstances, to use the simplified method in SAB 107 for employee option grants after December 31, 2007. Use of the simplified method after December 2007 is permitted only for companies whose historical data about their employees’ exercise behavior does not provide a reasonable basis for estimating the expected term of the options. The Company currently uses the simplified method to estimate the expected term for employee option grants as adequate historical experience is not available to provide a reasonable estimate. SAB 110 is effective for employee options granted after December 31, 2007. The Company adopted SAB 110 effective January 1, 2008 and continues applying the simplified method until enough historical experience is readily available to provide a reasonable estimate of the expected term for employee option grants.

Table of Contents

In June 2008, the FASB issued Staff Position EITF 03-06-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities" (FSP EITF 03-06-1). FSP EITF 03-06-1 provides that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method in SFAS No. 128, "Earnings per Share" and is effective for fiscal years beginning after December 15, 2008. We do not believe the implementation of FSP EITF 03-06-1 will have any impact on the Company's consolidated financial statements.

NOTE 3 - LOSS PER SHARE

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

	Years ended	
	2008	2007
Numerator - net loss available to common stockholders	$ (3,667,547)	$ (4,438,197)
Denominator - weighted average number of common shares outstanding	85,952,917	74,101,897
Basic and diluted loss per common share	$ (0.04)	$ (0.06)

NOTE 4 – PURCHASED IN-PROCESS RESEARCH AND DEVELOPMENT

On October 3, 2008, we purchased certain assets of Arbios Systems, Inc. in order to enhance and strengthen our current PICM-19 porcine liver cell line based bioartificial liver technology relating to the pig cell based liver device technology formerly known as "HepatAssist." We re-trademarked the device as "HepaMate."

The effective purchase price of $548,325 was charged to operations in 2008 as purchased in-process research and development expense and consists of:

Cash	$ 250,000
Contract Commitment, discounted @5% or $14,422	200,000
Series D warrants, at fair value	98,325
Assumed liabilities	-
Total effective acquisition price	$ 548,325

The deferred $200,000 payment is due and payable on the earlier of (i) the date on which we consummate one or more debt or equity financings in which the gross proceeds received in the aggregate equal or exceed $4,000,000, or (ii) the eighteen month anniversary of the closing date. The deferred payable does not bear interest. In accordance with

Accounting Principles Board (APB) Opinion No. 21 “Interest on Receivables and Payables,” we discounted the payable with an effective annual interest rate of 5% and the associated amortization of the discount is charged to interest expense over the 18 month expected life of the note. The contract commitment payable of $200,000 is recorded in noncurrent liabilities, net of unamortized discount of $12,873. For the year ended December 31, 2008, $1,549 of discount amortization was charged to interest expense.

Table of Contents

The fair value of the 750,000 Series D warrants issued in connection with this transaction was calculated as $98,325 using the Black-Scholes option pricing model with assumptions for a risk free interest rate of 2.64%, an expected life of 5 years, no dividend yield, and a volatility factor of 84.5%.

NOTE 5 - RELATED PARTY TRANSACTIONS

Director and Management Fees: For the year ended December 31, 2008, we incurred $19,343 in board fees for non-employee directors of the Company. In addition, during June and September 2008, we granted stock options to purchase 50,000 shares each for a total of 200,000 shares of common stock to non-employee board members. For the year ended December 31, 2008, we recorded $12,541 as stock compensation expense relating to these stock grants (refer to Note 10). During the year ended December 31, 2007, we paid management fees of $4,900 to non-employee directors. There is no management or consulting agreements in effect.

Legal Fees: In relation to our May 2008 Private Placement, we settled $21,250 in legal costs by issuing 50,000 Units to our attorney who also serves as a board member. Legal fees expensed for the year ended December 31, 2008 that were paid or are due to this attorney total $111,150.

Notes Payable and Accrued Interest: On May 23, 2008, we reached an agreement with Mr. Harmel Rayat to which Mr. Rayat (i) converted the entire outstanding principal amount ($877,800) of his loan to the Company into an aggregate of 2,065,412 Units, each Unit consisting of one share of the Company's common stock and one Series C warrant, at a conversion price of $0.425 per Unit and (ii) agreed to accept $150,000 in full payment and satisfaction of the accrued and unpaid interest on the loan in the amount of $249,945.

Rent: Until August 31, 2008, our administrative office was located at 1628 West 1st Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. This premise is owned by a private corporation controlled by Mr. Rayat. We paid rent of $26,866 for the year ended December 31, 2008 (2007: $35,740). Effective September 1, 2008, we closed this administrative office, terminating all of its employees. There were no severance arrangements with any of the terminated employees.

Mr. Harmel S. Rayat was an officer, director and majority stockholder of the Company until June 2008. All related party transactions are recorded at the exchange amount established and agreed to between related parties and are in the normal course of business.

NOTE 6 – EQUIPMENT

	December 31, 2008	December 31, 2007
Computer equipment	$ -	$ 37,382
Furniture and fixtures	-	1,089
	-	38,471
Less: accumulated depreciation	-	(27,589)
	$ -	$ 10,882

During the year ended December 31, 2008, we removed the cost and related accumulated depreciation for equipment that was either no longer in service or deemed obsolete. Substantially all of this equipment was located at the

Company's administrative office in Vancouver, British Columbia, Canada, which, effective September 1, 2008, was closed. We recorded a loss on disposal of fixed assets of $3,061 in the consolidated statement of operations for the year ended December 31, 2008.

Table of Contents

Depreciation expenses charged to operations for the years ended December 31, 2008 and 2007 were $7,821 and $16,255 respectively.

NOTE 7 - COOPERATIVE AND LICENSE AGREEMENTS

USDA, ARS CRADA: In November 2002, we entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS) pertaining to the continued development and use of patented liver cell lines in artificial liver devices and in-vitro toxicological testing platforms. This agreement was amended several times, with a final agreement termination date of November 2009. We terminated the CRADA effective November 30, 2008. For the years ended December 31, 2008 and 2007, costs charged to research and development expense under the CRADA totaled $268,359 and $144,103 respectively.

USDA, ARS License: On November 20, 2007, we exercised our license right under the CRADA by entering into an exclusive license agreement with the USDA, ARS for existing and future patents related to the PICM-19 hepatocyte cell lines. Under this license agreement, we incurred a license execution fee of $150,000 with $75,000 paid in December 2007 and $75,000 paid in November 2008. In addition to these payments during the first two years of the contract, we are responsible for annual license maintenance fees commencing in year 2010 for the term of the license, which is until the expiration of the last to expire licensed patents unless terminated earlier. These annual fees are capitalized to prepaid license costs when incurred and amortized to operating expense over the course of each year. The license agreement also requires certain milestone payments, if and when milestones are reached, as well as royalties on net sales of resulting licensed products, if any.

MSU License: On June 15, 2006, we entered into an exclusive worldwide license agreement with Michigan State University (MSU) through our subsidiary, Phoenix BioSystems, Inc. (PBS), for the development of new cell-culture based flu vaccines to protect against the spread of influenza viruses among humans, including potentially the high pathogenicity H5N1 virus. The license agreement was amended on February 2, 2008. The license agreement provides us exclusive rights to certain issued patents, for which we paid an initial fee of $1,000 upon execution of the agreement in 2006. The agreement requires royalties on net sales of resulting licensed products, if any, with minimum payments due commencing in year 2010 for the term of the license, which is until the expiration of the last to expire of the patents, or until fifteen (15) years after the effective date of June 15, 2006, whichever is longer.

We are also required to make certain milestone payments to MSU, if and when achieved.

As part of the license agreement, on October 2, 2006 PBS issued 17,650 common shares at par value, or 15% of the total issued and outstanding shares of PBS, to an individual who is also a member of the Company’s scientific advisory board. After issuance of the shares, we hold 85% of the total issued and outstanding shares of PBS. We recorded the fair value of the 15% issued shares at a nominal value. As PBS had no assets or liabilities, no value was allocated to the minority interest.

For the year ended December 31, 2007, we charged to research and development expense $32,426 relating to the MSU license, with no costs incurred during 2008 and costs incurred to date totaling $73,352. In January 2009, we provided notice to MSU to terminate the license agreement effective April 24, 2009. Any costs for the remainder of the license agreement term will be charged to operating expense as incurred.

NOTE 8 - CONVERTIBLE PROMISSORY NOTE

On May 11, 2007, we entered into a Securities Purchase Agreement with GCA Strategic Investment Limited for the sale of a convertible note with a $2,500,000 aggregate principal amount and maturity date of May 11, 2009. The convertible note was issued on May 11, 2007 at a purchase price of $2,125,000 (eighty-five per cent of the principal

amount). The convertible note does not bear interest, except upon an event of default at which time interest would accrue at the rate of 18% per annum. Under the terms of the agreement, the purchaser agreed not to effect, or cause any affiliate or associate to effect, a short sale of the Company's common stock. In connection therewith, we also issued to the purchaser warrants to purchase up to an aggregate of 670,000 shares of the Company’s common stock at a price of $1.50 per share (the warrants) for a term of five years.

Table of Contents

In connection with this transaction, we also agreed to pay the purchaser's adviser out of pocket fees of $15,000; and pay to Equinox Securities, Inc., a NASD registered broker/dealer, pursuant to an agreement dated April 19, 2007, 10% of the amount funded plus a warrant to purchase a number of shares of the Company's common stock equal to 10% of the number of shares subject to the warrants issued in connection with the convertible at the same exercise price of $1.50 per share, or 67,000 shares, in consideration of its efforts in securing, on behalf of the Company, the financing with the purchaser.

The convertible note contained a prepayment option and redemption feature under certain conditions and circumstances. A registration statement relating to the resale of the common shares issuable under the conversion of the convertible note and exercise of the warrants was declared effective on July 5, 2007.

Conversion of the Convertible Note

The convertible note (and any accrued and unpaid interest or liquidated damages amount) may be converted into shares of the Company's common stock at a conversion price of 95% of the trading volume weighted average price, as reported by Bloomberg LP (the "VWAP"), for the five trading days immediately prior to the date of notice of conversion.

In 2007, $1,745,000 of the convertible note was converted into 2,604,721 shares of common stock. In January 2008, the remaining $755,000 of the convertible note was converted into 2,342,415 shares of common stock. For the year ended December 31, 2008, the remaining discount of $468,343 (2007: $1,624,756) and issuance costs of $210,728 (2007: $82,787) relating to the convertible note were charged to operations.

Bifurcation of the Warrants from the Convertible Note and the Intrinsic Value of the Beneficial Conversion Feature of the Note

The convertible note contained a conversion feature that allowed the holder to convert the debt into equity shares at any time within a specified period at a price equal to 95% of the volume weighted average price of the Company's common shares for the five trading days prior to the conversion date. As the host contract did not embody a claim to the residual interest in the Company, the economic characteristics and risks of the host contract was considered that of a debt instrument and classified as a liability.

We determined that the embedded conversion option did not meet the definition of a derivative as described under SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" paragraph 12(a) and 12(c) as the conversion option results in a fixed monetary benefit to the holder known at the measurement date.

The convertible note was a complex hybrid instrument bearing an option, the alternative choices of which could not exist independently of one another. Thus, the beneficial conversion feature could not be separated from the debt according to paragraph 7 and 12 of APB Opinion No. 14 "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants" (ABP 14). The embedded beneficial conversion feature was recognized and measured in accordance with paragraph 5 of EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" (EITF 98-5) and paragraph 5 of EITF 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments" (EITF 00-27), whereby the intrinsic value of the beneficial conversion feature was calculated at the commitment date as the difference between the effective conversion price of the convertible note and the fair value of the common stock into which the convertible note was convertible, multiplied by the number of shares into which the convertible note was convertible. The intrinsic value of the beneficial conversion feature, $1,220,410, was treated as a discount on issuance of the convertible note and amortized over the life of the convertible note (paragraph 10 of EITF 98-5 and paragraph 19 of EITF 00-27).

The warrants are detached from the convertible note with no put option feature. There is no liquidated damage or cash penalty payable to the warrant holder if the Company was not able to register the shares underlying the warrants. According to paragraph 16 of APB 14, the portion of the proceeds of the convertible note issued with the detachable warrants which is allocable to the warrants is accounted for as paid-in capital. The allocation was based on the relative fair values of the two securities at the time of issuance. The portions of the proceeds allocated to the convertible note and warrants were $1,627,311 and $497,689 (refer to Note 9), respectively. The resultant debt discount was amortized over the life of the convertible note (paragraph 16 of APB14).

Table of Contents

NOTE 9 – STOCKHOLDERS' EQUITY (DEFICIT)

Under the New Purchase Agreement with Fusion Capital Fund II ("Fusion Capital") dated January 20, 2006, Fusion Capital had agreed to purchase from the Company up to $15,000,000 of the Company's shares of common stock over a thirty month period. During the years ended December 31, 2007 and 2006, Fusion Capital had purchased 891,019 and 2,154,661 shares of common stock of the Company for total proceeds of $495,001 and $1,719,996, respectively. On May 11, 2007, the Company and Fusion Capital mutually terminated the Common Stock Purchase Agreement. The Company did not incur any termination costs as a result of mutually terminating this agreement.

On May 23, 2008, we completed a private placement of 10,660,705 units at a price of $0.425 per unit or $4,530,800 in the aggregate. Each unit consists of one share of the Company's common stock and one Series C stock purchase warrant (Series C warrant) to purchase a share of common stock at the initial exercise price of $0.55 per share for a period of two years from the date of issuance. The relative fair value of the common stock was estimated to be $2,972,407 and the relative fair value of the warrants was estimated to be $1,558,393 as determined based on the relative fair value allocation of the proceeds received. The warrants were valued using the Black-Scholes option pricing model. In conjunction with our completion of the acquisition of the HepatAssist related assets in October 2008, we reduced the initial exercise price of the Series C warrants to $0.34 per share. In connection with the private placement, the agent was due a sales commission equal to $90,828 or two (2%) percent of the gross proceeds, which was settled by issuing to the agent 213,713 units. In addition, we issued an aggregate of 50,000 units in payment of legal fees in the amount of $21,250 (refer to Note 5). These units were otherwise issued on the same terms and conditions as the units sold in the private placement.

Pursuant to the Subscription Agreement and the Registration Rights Agreement relating to the private placement, the Company and the investor parties made other covenants and representations and warranties regarding matters that are customarily included in financings of this nature. In the event that during the twelve month period following the closing date the Company issues shares at a price per share which is less than $0.425 per share (the "Base Share Price"), then the Company is required to issue to the investors the number of shares equal to (1) the quotient of the aggregate purchase price payable under the Securities Purchase Agreement divided by Base Share Price less (2) the quotient of the aggregate purchase price divided by the per share purchase price under the Securities Purchase Agreement.

On August 18, 2008, the Board of Directors agreed to issue 400,000 shares of its restricted common stock for services provided by its investment banker for the period January 1, 2008 to August 31, 2008. The value of the issuance was agreed to be the value of services provided, $170,000. These shares were issued November 8, 2008.

Warrants

We account for warrants granted to unrelated parties in accordance with EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock." In accordance with the EITF, the fair value of such warrants is classified as a component of permanent equity within additional paid-in capital and is calculated on the date of grant using the Black-Scholes Option pricing model.

Each of the Company's warrants outstanding entitles the holder to purchase one share of the Company's common stock for each warrant share held. No warrants were exercised during the years ended December 31, 2008 and 2007. A summary of the Company's warrants outstanding, which are also described in Notes 4, 5, and 8, is as follows:

	Warrants	Series C Warrants	Series D Warrants
Warrants outstanding and exercisable at December 31, 2008	737,000	12,989,830	750,000
Exercise price	$ 1.50	$ 0.34	$ 0.35

Fair value on date of grant	$ 714,890	$ 1,898,867	$ 98,325
Black-Scholes option pricing model assumptions:			
Risk-free interest rate	4.58%	2.46%	2.64%
Expected term	5 years	2 years	5 years
Expected volatility	96.20%	94.10%	84.50%
Dividend per share	$ 0	$ 0	$ 0
Expiration date	May 11, 2012	May 23, 2010	October 3, 2013

Table of Contents

A total of 14,476,830 shares of the Company's common stock have been reserved for issuance upon exercise of warrants shares outstanding as of December 31, 2008.

NOTE 10 - STOCK OPTIONS

We have an active stock option plan that provides shares available for option grants to employees, directors and others. A total of 40,000,000 shares of the Company's common stock have been reserved for award under the stock option plan, of which 35,098,000 were available for future issuance as of December 31, 2008. Options granted under the Company's option plan generally vest over two to five years or as otherwise determined by the Board of Directors, have exercise prices equal to the fair market value of the common stock on the date of grant, and expire no later than ten years after the date of grant.

Stock option activity during the years ended December 31, 2008 and 2007 is summarized as follows:

	Number of options	Weighted average exercise price	Remaining contractual term	Aggregate intrinsic value
Outstanding at December 31, 2006	10,350,000	$ 0.67		
Granted	2,026,750	0.52		
Cancelled	(10,350,000)	0.67		
Outstanding at December 31, 2007	2,026,750	0.52		
Granted	775,000	0.54		
Cancelled	(101,750)	0.43		
Outstanding at December 31, 2008	2,700,000	0.53	8.44	$ -
Exercisable at December 31, 2008	100,000	0.61	9.45	-
Available for grant at December 31, 2008	35,098,000			

The aggregate intrinsic value in the table above represents the total pretax intrinsic value for all "in-the-money" options (i.e. the difference between the Company's closing stock price on the last trading day of the year ended December 31, 2008 and the exercise price, multiplied by the number of shares) that would have been received by the option holders had all option holders exercised their options on December 31, 2008. This amount is based on the fair market value of the Company's stock. Total intrinsic value of options exercised was $nil at December 31, 2008 (2007: $nil).

A summary of the Company's unvested stock options and changes during the years ended December 31, 2008 and 2007 is as follows:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested, December 31, 2006	4,650,000	$ 0.51
Granted	2,026,750	0.43
Cancelled	(4,650,000)	0.51
Unvested, December 31, 2007	2,026,750	0.43
Granted	775,000	0.37
Vested	(100,000)	0.41

Cancelled	(101,750)	0.26
Unvested, December 2008	2,600,000	0.42

The following table details further information regarding stock options outstanding and exercisable at December 31, 2008:

33

Table of Contents

Range of Exercise Prices	Outstanding Number Outstanding at December 31, 2008	Outstanding Weighted Average Remaining Contractual Life (Years)	Outstanding Weighted Average Exercise Price	Exercisable Number Exercisable at December 31, 2008	Exercisable Weighted Average Exercise Price
$ 0.52	2,000,000	8.07	$ 0.52	-	$ -
0.61	550,000	9.45	0.61	100,000	0.61
0.57	50,000	9.47	0.57	-	-
0.25	100,000	9.70	0.25	-	-
$ 0.53	2,700,000	8.44	$ 0.53	100,000	$ 0.61

During the years ended December 31, 2008 and 2007, we granted 775,000 and 2,026,750 stock options awards. For purposes of determining the stock-based compensation expense for stock option awards granted, the Black-Scholes option-pricing model was used with the following weighted-average assumptions:

	2008 Stock Option Grants	2007 Stock Option Grants
Risk-free interest rate	2.75% - 3.57%	3.41% - 4.85%
Expected term	5 years	4.7 - 5 years
Expected volatility	83.32% - 90.53%	93.95% - 94.73%
Weighted-average volatility	84.2%	94.0%
Dividend per share	$0	$0

The weighted average fair value of options granted during the year ended December 31, 2008 was $0.37 (2007: $0.43) per share.

During the year ended December 31, 2008, total compensation expense charged to operations was $565,306 (2007: $935,044), with $552,765 classified as salaries and benefits and $12,541 included in director fees. As of December 31, 2008, the Company had $285,286 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of approximately 8.40 years. The fair value of stock options that vested during the year ended December 31, 2008 was $41,000.

We do not repurchase shares to fulfill the requirements of options that are exercised. Further, we issue new shares when options are exercised.

NOTE 11 – INCOME TAXES

There is no current or deferred tax expense for the years ended December 31, 2008 and 2007 due to the Company’s loss position. The benefits of temporary differences have not been 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 sheets is primarily a result of stock compensation costs, research and development costs, and of start-up expenses, which are capitalized for income tax purposes. Net deferred tax assets are summarized as follows:

Table of Contents

	2008	2007
Net operating loss carryforwards	$ 3,180,000	$ 2,262,000
Stock compensation costs	1,397,000	1,204,000
Other	566,000	683,000
	5,143,000	4,149,000
Valuation allowance	(5,143,000)	(4,149,000)
Net deferred tax assets	$ -	$ -

The 2008 increase in the valuation allowance was $994,000 (2007: $957,000).

The Company has available net operating loss carryforwards of approximately $9,534,000 for tax purposes to offset future taxable income which expire commencing 2009 to 2028. Additionally, research and development, start-up costs of approximately $1,665,000 are available to reduce taxable income assuming normal operations have commenced. The tax years 2006 through 2008 remain open to examination by federal authorities and other jurisdictions of which the company operates.

A reconciliation between the statutory federal income tax rate (34%) and the effective rate of income tax expense for 2008 and 2007 is as follows:

	2008	2007
Statutory federal income tax	-34.00%	-34.00%
Valuation allowance	32.00	34.00
Stock offering costs	2.00	-
Effective income tax rate	0.00%	0.00%

Table of Contents

ITEM 9: CHANGE IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

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

ITEM 9A(T): CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), as of the end of the period covered by this annual report. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded as of December 31, 2008 that the Company's disclosure controls and procedures were effective such that the information required to be disclosed in the Company's United States Securities and Exchange Commission (the "SEC") reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Evaluation of and Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting of the Company. Management, with the participation of our chief executive officer and chief financial officer, has evaluated the effectiveness of our internal control over financial reporting as of December 31, 2008 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations (COSO). Based on this evaluation, management concluded that, as of December 31, 2008, our internal control over financial reporting is effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

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 9B. OTHER INFORMATION.

None.

Table of Contents

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table and text set forth the names and ages of all of our directors and executive officers as of December 31, 2008. The board of directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal.

Name	Age	Position	Director/Officer Since
Frank Menzler	40	President, Chief Executive Officer, Chairman, Interims Chief Financial Officer and Director	October 2006
Jatinder Bhogal	41	Director	September 2008
Javier Jimenez	43	Director	March 2007
Roland Schomer	43	Director	June 2008
Joseph Sierchio	58	Director	September 2008

There are no family relationships between or among the directors, executive officers or persons nominated or charged by our company to become directors or executive officers. Executive officers are appointed by, and serve at the discretion of, the Board of Directors.

Recent Management Changes:

(1) On September 12, 2008, Mr. Harmel S. Rayat, resigned as the Company’s Secretary, Treasurer, Chief Financial Officer, and as a director. Mr. Rayat resigned for personal reasons and not as a result of any disagreement between himself and the Company or the Board of Directors.

(2) On October 6, 2008 Mr. Frank Fabio, accepted an appointment to serve, on an interim basis, as the Company’s Chief Financial Officer. On November 14, 2008, Mr. Frank Fabio resigned as the Company’s Interim Chief Financial Officer and Secretary; Mr. Fabio resigned in order to devote more time to his other endeavors and not as a result of any disagreement between himself and the Company.

(3) On March 14, 2007 Mr. Arian Soheili and Mr. Jasvir Kheleh resigned from their positions as directors. Mr. Soheili and Mr. Kheleh resigned for personal reasons and not as a result of any disagreement between himself and the Company or the Board of Directors.

The following is a brief description of the business experience of each director and executive officer during the past five years and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws.

FRANK MENZLER. Mr. Menzler earned a ‘Diplom-Ingenieur’ (Master’s of Science equivalent) in Mechanical and Biomedical Engineering from RWTH Aachen, Germany’s largest university of technology in 1996, and his Master’s degree in Business Administration (MBA) from Northwestern University’s, Kellogg School of Management in 2001. In 1998, Mr. Menzler co-founded Impella Cardiotechnik AG (Germany), helping to raise more than $30 million in grants and venture capital for one of the nation's first academically-sponsored research effort to receive private venture capital funding. In 2002, Mr. Menzler served as Marketing Manager for Europe, Middle East, Africa and Canada (EMEAC) at Guidant Corporation's, Cardiac Surgery Business Unit in Brussels, Belgium. In 2004,

Mr. Menzler joined Abiomed, Inc. as General Manager, Europe, and then in 2006 was named Director, International Distributors, and was responsible for sales, training and operations. Prior to his appointment as our President, Chief Executive Officer, Director, Mr. Menzler was a member of our Scientific Advisory Board. He was appointed Chairman of HepaLife Technologies, Inc. on June 11, 2008. On November 14, 2008 he was appointed Interims Chief Financial Officer.

Table of Contents

JAVIER JIMENEZ. Mr. Jimenez received both Bachelor and Masters degrees in Aeronautical Engineering from Universidad Politecnica de Madrid, Spain in 1991, and his Master's degree in Business Administration (MBA) from Boston University in 1996. In 2000, Mr. Jimenez joined GE Healthcare, a division of General Electric Company. During his tenure at GE Healthcare, Mr. Jimenez held several key finance and management positions, including eBusiness Finance Manager (Latin America), Finance Manager (Brazil), Finance Manager (Latin American Distributors), Manager, Financial Planning & Analysis, Manager, Global PET Operations and Director, Commercial Operations, in the United States and Latin America. In 2004, Mr. Jimenez joined ABIOMED, Inc., the developer of the world's first self-contained artificial heart, as Vice President, Operations. Mr. Jimenez served in numerous positions, most recently, as Vice President, General Manager Europe. In 2008 Mr. Jimenez became Partner in the New England practice of Tatum, LLC. a firm that provides companies with executive services and consulting, helping to maximize the Office of the CFO. Mr. Jimenez joined the Board of Directors on March 14, 2007.

ROLAND SCHOMER. In 2001, Dr. Schomer joined Actelion Pharmaceuticals Deutschland GmbH, where he built the company's German affiliate as General Manager, Germany. In 2003, Dr. Schomer served as Business Director, Europe, Middle East and Africa, for Actelion Pharmaceuticals Ltd. in Switzerland. In 2004, Dr. Roland Schomer joined Novartis Pharma AG in Basel, Switzerland, where he currently serves as Global Brand Director, Transplantation. Dr. Schomer joined the Board of Directors on June 18, 2008. Dr. Roland Schomer holds a Medical degree from Medical School of Johannes-Gutenberg University in Mainz, Germany, and subsequently completed his MBA from Northwestern University's Kellogg School of Management.

JATINDER S. BHOGAL. Since December 1993, Mr. Bhogal has worked as a business consultant to emerging growth companies. For over 15 years, Mr. Bhogal has provided early business development guidance and consulting to companies developing healthcare services, medical devices, pharmaceuticals and vaccines, solar-photovoltaics, biofuels, and information technology solutions.

JOSEPH SIERCHIO. Since 1975, Mr. Sierchio has practiced corporate and securities law in New York City, representing and offering counsel to domestic and foreign corporations, investors, entrepreneurs, and public and private companies in the United States, Canada, United Kingdom, Germany, Italy, Switzerland, Australia, and Hong Kong. Mr. Sierchio is admitted in all New York state courts and federal courts in the Eastern, Northern, and Southern Districts of the State of New York as well as the federal Court of Appeals for the Second Circuit. Mr. Sierchio earned his Doctor of Law degree at Cornell University Law School in 1974, and a Bachelor of Arts degree, with Highest Distinction in Economics, from Rutgers College at Rutgers University, in 1971. Mr. Sierchio is also a member of Sierchio & Company, LLP, counsel to the Company.

During the past five years none of our directors, executive officers, 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.

Director Independence

As of the date of this Report, because none of our securities is listed on a national securities exchange or in an inter-dealer quotation system we are not required to have a majority of independent directors . However, after considering all of the relevant facts and circumstances, the Board of Directors has determined that Messrs. Jimenez and Sierchio, as well as Dr. Schomer are independent from our management and qualify as “independent directors” under the standards of independence set forth in Rule 4200(15) of the NASDAQ Stock Market Rules. This means that, in the judgment of the Board of Directors none of Messrs. Jimenez and Sierchio, as well as Dr. Schomer (1) is an officer or employee (during the prior three fiscal years) of the Company or its subsidiaries or (2) has any direct or indirect relationship with the Company that would interfere with the exercise of his independent judgment in carrying out the responsibilities of a director.

Table of Contents

Code of Ethics

Effective December 31, 2008, our Board of Directors adopted an Amended and Restated Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer. We are committed to the highest standards of ethical and professional conduct, and the code provides guidance in how to uphold these standards. The code consists of basic standards of business practice as well as professional and personal conduct.

Compliance With Section 16(a) Of The Exchange Act

Based solely upon our review of Forms 3 and 4 and amendments thereto furnished to us by each of Messrs. Menzler, Rayat and Jimenez pursuant to Rule 16a-3(e) of during our current fiscal year and Form 5 and the amendments thereto furnished to us with respect to our most recent fiscal year, we believe that all of our directors, executive officers and persons who own more than 10% of our common stock were in compliance with Section 16(a) of the Exchange Act of 1934 during the fiscal year except for Messrs. Bhogal and Sierchio who did not timely file their respective initial Form 3s following election to our Board of Directors. During the fiscal 2007, all of our directors, executive officers and persons who own more than 10% of our common stock were in compliance with section 16(a) of the Exchange Act of 1934.

Directors

Our board of directors currently consists of five members. Directors serve for a term of one year and stand for election at our annual meeting of stockholders. Pursuant to our Bylaws, any vacancy occurring in the board of directors, including a vacancy created by an increase in the number of directors, may be filled by the stockholders or by the affirmative vote of a majority of the remaining directors though less than a quorum of the board of directors. A director elected to fill a vacancy shall hold office only until the next election of directors by the stockholders. If there are no remaining directors, the vacancy shall be filled by the stockholders.

At a meeting of stockholders, any director or the entire board of directors may be removed, with or without cause by our stockholders, provided the notice of the meeting of our stockholders states that one of the purposes of the meeting is the removal of the director. A director may be removed only if the number of votes cast to remove him exceeds the number of votes cast against removal.

Currently we do not have any committees.

Compensation of Directors

In 2008 and 2007, we incurred $19,343 and $4,900, respectively, in fees to directors. Stock-based compensation expense relating to director stock option awards totaled $12,541 for the year ended December 31, 2008.

Each non employee director receives an initial stock option entitling him to purchase up to 50,000 shares of stock at a price per share equal to the closing price of our common stock, as reported on the Over the Counter Bulletin Board on the date of the option grant; the options vest at the rate of 20% per annum in arrears. In addition each non-employee director receives a quarterly cash payment, in arrears, of $2,500. Each director is entitled to reimbursement of out of pocket expenses incurred in connection with his services as a Director of the Company.

We have no other arrangements pursuant to which any our directors were compensated during the years ended December 31, 2008 and 2007 for services as a director.

ITEM 11: EXECUTIVE COMPENSATION.

The following table shows, for the three-year period ended December 31, 2008, the cash compensation paid by the Company, as well as certain other compensation paid or accrued for such year, to the Company's Chief Executive Officer and the Company's other most highly compensated executive officers. Except as set forth on the following table, no executive officer of the Company had a total annual salary and bonus for 2008 that exceeded $100,000.

Table of Contents

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Other	Securities Underlying Options Granted	All Other Compensation
Frank Menzler	2008	$ 225,000	$ 0	$ 0	500,000	$ 0
President, CEO	2007	$ 225,000	$ 0	$ 0	2,000,000	$ 0
Chairman, and Director	2006	$ 56,250	$ 0	$ 0	0	$ 0
Harmel S. Rayat (1)	2008	$ 0	$ 0	$ 0	0	$ 0
Former Secretary,						
Treasurer	2007	$ 0	$ 0	$ 0	0	$ 0
Chief Financial Officer	2006	$ 0	$ 0	$ 0	0	$ 0
Chairman, and Director						
Arian Soheili (2)	2008	$ 0	$ 0	$ 0	0	$ 0
Former CEO, Secretary,	2007	$ 0	$ 0	$ 1,050	0	$ 0
Treasurer, Director	2006	$ 0	$ 0	$ 3,600	0	$ 0

(1) Resigned as an officer and director on September 12, 2008.

(2) Includes standard Board of Directors fees. Resigned as Secretary, Treasurer and Director on March 14, 2007

Stock Option Grants in Last Fiscal Year

Shown below is further information regarding stock options awarded during 2008 to the named officers and directors:

Name	Number of Securities Underlying Options	% of Total Options Granted to Employees in 2008	Exercise Price ($/sh)	Expiration Date
Frank Menzler	500,000	71%	$ 0.61	6/11/2018
Harmel Rayat(1)	0	0	n/a	n/a
Javier Jimenez	50,000	7%	0.61	6/11/2018
Roland Schomer	50,000	7%	0.61	6/11/2018
Jatinder Bhogal	50,000	7%	0.26	9/12/2018
Joseph Sierchio	50,000	7%	0.26	9/12/2018

(1) Resigned as an officer and director on September 12, 2008.

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:

Table of Contents

Name	Common Shares Underlying Unexercised Options on December 31, 2008		Value of Unexercised In-the-money Options on December 31, 2008	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Frank Menzler	100,000	2,400,000	$ 0	$ 730,000
Harmel Rayat (1)	0	0	0	0
Javier Jimenez	0	50,000	0	0
Roland Schomer	0	50,000	0	0
Jatinder Bhogal	0	50,000	0	0
Joseph Sierchio	0	50,000	0	0
Arian Soheili (2)	0	0	0	0
Jasvir Kheleh (3)	0	0	0	0

(1) Resigned as an Officer and Director on September 12, 2008.
(2) Resigned as an Officer and Director on March 14, 2007
(3) Resigned as a Director on March 14, 2007

Employment Contracts and Change in Control Arrangements

Except for our agreement with Mr. Menzler, we do not have any employment agreements with any of our officers and directors. On October 1, 2006, the Company and Mr. Menzler entered into an employment agreement whereas Mr. Menzler: (i) agreed to serve as President and Chief Executive Officer, (ii) will receive an annualized base salary of $225,000, (iii) has been granted options to purchase up to 2,250,000 shares of the Company's common stock at an exercise price of $0.73. Subsequently, on January 25, 2007, the Company agreed (simultaneously with the termination of 2,250,000 stock options) to enter a stock option agreement with Mr. Frank Menzler for 2,000,000 common shares at an exercise price of $0.52 per share. On June 11, 2008, the Company agreed to enter a stock option agreement with Mr. Frank Menzler for 500,000 common shares at an exercise price of $0.61 per share.

The Company does not have any change-of-control or severance agreements with any of its executive officers or directors. In the event of the termination of employment of the Named Executive Officers any and all unexercised stock options shall expire and no longer be exercisable after a specified time following the date of the termination.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth, as of December 31, 2008, 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.

Person or Group	Number of Shares of Common Stock	Percent
Frank Menzler (1) 60 State Street, Suite 700 Boston, MA 02109	100,000	<1%
Javier Jimenez 60 State Street, Suite 700	0	0%

Boston, MA 02109		
Roland Schomer(2) 60 State Street, Suite 700 Boston, MA 02109	7,000	<1%
Jatinder S. Bhogal 60 State Street, Suite 700 Boston, MA 02109	0	0%
Joseph Sierchio(3) 60 State Street, Suite 700 Boston, MA 02109	100,000	<1%
Harmel S. Rayat (4) 216-1628 West First Avenue Vancouver, B.C. V6J 1G1 Canada	33,228,468	36%
Directors and Executive Officers as a group (5 persons)	207,000	<1%

Table of Contents

1. Represents shares issuable pursuant to options granted on June 11, 2008 and vested on October 1, 2008.
2. Represents 7,000 shares acquired by Mr. Schomer in open market transactions in 2007 prior to his election to our Board of Directors.
3. Represents 50,000 shares of our common stock acquired by Mr. Sierchio in the private placement we completed in May 2008 and 50,000 shares issuable pursuant to Series C Warrants at an exercise price of $0.34 per share.
4. This amount includes 30,025,274 shares held by 1420525 Alberta Ltd., a private Alberta company wholly-owned by Mr. Rayat and 3,203,194 shares held by Tajinder Chohan, Mr. Rayat's wife.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Director and Management Fees: For the year ended December 31, 2008, we incurred $19,343 in board fees for non-employee directors of the Company. In addition, during June and September 2008, we granted stock options to purchase 50,000 shares each for a total of 200,000 shares of common stock to non-employee board members. For the year ended December 31, 2008, we recorded $12,541 as stock compensation expense relating to these stock grants (refer to Note 10). During the year ended December 31, 2007, we paid management fees of $4,900 to non-employee directors. There is no management or consulting agreements in effect.

Legal Fees: In relation to our May 2008 Private Placement, we settled $21,250 in legal costs by issuing 50,000 Units to our attorney who also serves as a board member. Legal fees expensed for the year ended December 31, 2008 that were paid or were due to this attorney total $111,150.

Notes Payable and Accrued Interest: On May 23, 2008, we reached an agreement with Mr. Harmel Rayat to which Mr. Rayat (i) converted the entire outstanding principal amount ($877,800) of his loan to the Company into an aggregate of 2,065,412 Units, each Unit consisting of one share of the Company's common stock and one Series C warrant, at a conversion price of $0.425 per Unit and (ii) agreed to accept $150,000 in full payment and satisfaction of the accrued and unpaid interest on the loan in the amount of $249,945.

Rent: Until August 31, 2008, our administrative office was located at 1628 West 1st Avenue, Suite 216, Vancouver, British Columbia, Canada, V6J 1G1. This premise is owned by a private corporation controlled by Mr. Rayat. We paid rent of $26,866 for the year ended December 31, 2008 (2007: $35,740). Effective September 1, 2008, we closed this administrative office, terminating all of our employees at this location. There were no severance arrangements with any of the terminated employees.

Mr. Harmel S. Rayat was an officer and director of the Company until September 12, 2008 and a majority stockholder of the Company until September 9, 2008.

Table of Contents

All related party transactions are recorded at the exchange amount established and agreed to between related parties and are in the normal course of business.

Director Independence.

Please refer to “ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.”

ITEM 14: PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The firm of Peterson Sullivan, LLP 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.

The Company does not currently have an audit committee.

The following table presents aggregate fees for professional services rendered by Peterson Sullivan, LLP for the years ended December 31, 2008 and 2007.

	Year Ended December 31, 2008	Year Ended December 31, 2007
Audit fees	$ 24,582	$ 25,770
Audit-related fees	-	-
Tax fees	11,457	-
All other fees	-	-
Total	$ 36,039	$ 25,770

Table of Contents

PART IV

ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) The following exhibits are filed as part of this Form 10-K:

1. Financial Statements

The following financial statements are included in Part II, Item 8 of this Form 10-K:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2008 and 2007
- Consolidated Statements of Operations for the years ended December 31, 2008 and 2007, and from Inception (October 21, 1997) to December 31, 2008
- Consolidated Statements of Stockholders' Equity (Deficit) from Inception (October 21, 1997) to December 31, 2008
- Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007, and from Inception (October 21, 1997) to December 31, 2008
- Notes to Consolidated Financial Statements

2. Financial Statement Schedules.

Financial statement schedules are omitted because they are not required or are not applicable, or the required information is provided in the consolidated financial statements or notes described in Item 15(a)(1) above.

Table of Contents

3. Other Exhibits to this Form 10-K:

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

Table of Contents

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 10-K for the fiscal year ended December 31, 2008, to be signed on its behalf by the undersigned, thereunto duly authorized on this 30th day of March, 2009.

HepaLife Technologies, Inc

/s/ Frank Menzler
Frank Menzler
President and CEO and
Chairman of the Board of Directors

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/ Frank Menzler Frank Menzler	Director , Chairman of the Board, President and Chief Executive Officer	March 30, 2009
/s/ Donna A. Lopolito Donna A. Lopolito	Chief Financial Officer	March 30, 2009
/s/ Jatinder S. Bhogal Jatinder S. Bhogal	Director	March 30, 2009
/s/ Javier Jimenez Javier Jimenez	Director	March 30, 2009
/s/ Roland Schomer Roland Schomer	Director	March 30, 2009
/s/ Joseph Sierchio Joseph Sierchio	Director	March 30, 2009