HEPALIFE TECHNOLOGIES INC
Form 8-K
December 21, 2004

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

December 15, 2004

Date of Report (Date of earliest event reported)

HEPALIFE TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Florida

(State or other jurisdiction of incorporation)

000-29819

(Commission File Number)

58-2349413

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

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

(Address of principal executive offices)

(800) 518-4879

(Registrant s telephone number, including area code)

SECTION 1. Registrant's Business and Operations

None.

SECTION 2. Financial Information

None.

SECTION 3. Securities and Trading Markets

None.

SECTION 4. Matters Related to Accountants and Financial Statements

None.

SECTION 5. Corporate Governance and Management

None.

SECTION 6. [Reserved]

N/A.

SECTION 7. Regulation FD

Except for the historical information presented in this document, the matters discussed in this Form 8-K, or otherwise incorporated by reference into this document, contain "forward-looking statements" (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are identified by the use of forward-looking terminology such as "believes", "plans", "intend", "scheduled", "potential", "continue", "estimates", "hopes", "goal", "objective", expects", "may", "will", "should" or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. The safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, apply to forward-looking statements made by the Registrant. The reader is cautioned that no statements contained in this Form 8-K should be construed as a guarantee or assurance of future performance or results. These forward-looking statements involve risks and uncertainties, including those identified within this Form 8-K. The actual results that the Registrant achieves may differ materially from any forward-looking statements due to such risks and uncertainties. These forward-looking statements are based on current expectations, and the Registrant assumes no obligation to update this information. Readers are urged to carefully review and consider the various disclosures made by the Registrant in this Form 8-K and in the Registrant'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 Registrant's business.

Note: Information in this report furnished pursuant to Item 7 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this current report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended. The furnishing of the information in this current report is not intended to, and does not, constitute a representation that such furnishing is required by Regulation FD or that the information this current report contains is material investor information that is not otherwise publicly available.

On December 15, 2004, HepaLife Technologies, Inc. issued a news release to announce its expectations of increased drug induced liver injuries and adverse drug reactions due to a dramatic rise in prescription drug usage amongst Americans, with almost half of the population now taking at least one prescription drug and one person in every six taking three or more (Centers for Disease Control and Prevention, December 2, 2004). This news release, dated December 15, 2004, is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

SECTION 8. Other Events

None.

SECTION 9. Financial Statements and Exhibits

The following exhibits are furnished as part of this report:

Exhibit 99.1 Press Release dated December 15, 2004

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HEPALIFE TECHNOLOGIES, INC.

/s/ Arian Soheili

Arian Soheili

President and CEO

Date: December 21, 2004

EXHIBIT 99.1

Drug induced liver injury expected to increase with almost half of all Americans now using prescription drugs.

Vancouver, BC December 15, 2004 - HepaLife Technologies, Inc. (OTCBB: HPLF), a development stage biotechnology company focused on the research, development and eventual commercialization of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease, today announces its expectations of increased drug induced liver injuries and adverse drug reactions due to a dramatic rise in prescription drug usage amongst Americans, with almost half of the population now taking at least one prescription drug and one person in every six taking three or more (Centers for Disease Control and Prevention, December 2, 2004).

The recent CDC report highlights the fact that we re living in an over-medicated society and confirms why we have such a high incidence of drug induced liver disease, states Mr. Harmel S. Rayat, Chairman of HepaLife. When taking multiple drugs there is the chance of interactions, making some medications ineffective, or worse still, causing serious harm to the liver the main organ in the body responsible for the detoxification of drugs. When drugs are ingested in high amounts, or in combinations with other drugs, alcohol or poisons, the toxic overload can destroy the liver quickly.

Adverse drug reactions are an increasingly important clinical problem in medicine today and rank among the ten most common causes of death (Hepatotoxicity Clinical Research Network). While drug induced liver injury occurs in all age groups, a greater percentage occurs in the elderly, where five out of six persons 65 and older are taking at least one medication and almost half are of the elderly take three or more. Drug induced liver injury is also the most common reason why drugs are not approved by FDA (about one third of all drugs fail pre-clinical or clinical trials due to the toxic nature of the compounds being tested) or are removed from the market following FDA approval. Examples of recent post-market discoveries include Accolate (asthma drug), Duract (analgesic and anesthetic) and Rezulin (diabetes), all linked to liver damage.

In response to the growing number individuals suffering from liver disease as a result of drug overdoses or interactions, rampant alcohol abuse and the worldwide hepatitis epidemic, HepaLife Technologies is developing the first of its kind artificial liver device incorporating the PICM-19H cell line, which has now been in continuous culture for over two years without presenting any detectable changes in hepatocyte morphology and function, a significant achievement.

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

The PICM-19H cells grown in vitro synthesize liver specific proteins such as albumin and transferrin, and display enhanced liver-specific functions such as ureagenesis and cytochrome P450 activity. As a result, HepaLife, using its exclusive cell line, plans to develop proprietary in vitro toxicological and pre-clinical drug testing platforms that will more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

ABOUT HEPALIFE TECHNOLOGIES, INC.

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

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

Artificial Liver Device

Presently, through a Cooperative Research and Development Agreement, HepaLife Technologies is working towards optimizing the hepatic functionality of the patented PICM-19 cell line. The hepatic characteristics of the PICM-19 cell line have been demonstrated to have potential application in the production of an artificial liver device for use by human patients with liver failure.

With 25 million Americans suffering from liver disease, the need for an artificial liver device able to remove toxins and improve immediate and long-term survival results is more critical today than ever before. Limited treatment

options, a low number of donor organs, the high price of transplants and follow up costs, a growing base of hepatitis, alcohol abuse, drug overdoses, and other factors that result in liver disease all clearly indicate a strong need for an artificial liver device.

In Vitro Toxicology Testing

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

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

The PICM-19 cells grown in vitro synthesize liver specific proteins such as albumin and transferrin, and display enhanced liver-specific functions such as ureagenesis and cytochrome P450 activity. As a result, HepaLife, using the patented PICM-19 cell line, plans to develop proprietary in vitro toxicological and pre-clinical drug testing platforms that will more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

For additional information, please visit www.hepalife.com

To receive future press releases via email, please visit http://www.hepalife.com/Alerts-Index.asp

Legal Notice Regarding Forward-Looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although the Company believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, it can give no assurance that such expectations and assumptions will prove to have been correct. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous factors and uncertainties,

including but not limited to adverse economic conditions, intense competition, lack of meaningful research results, entry of new competitors and products, adverse federal, state and local government regulation, inadequate capital, unexpected costs and operating deficits, increases in general and administrative costs, termination of contracts or agreements, technological obsolescence of the Company's products, technical problems with the Company's research and products, price increases for supplies and components, litigation and administrative proceedings involving the Company, the possible acquisition of new businesses or technologies that result in operating losses or that do not perform as anticipated, unanticipated losses, the possible fluctuation and volatility of the Company's operating results, financial condition and stock price, losses incurred in litigating and settling cases, dilution in the Company's ownership of its business, adverse publicity and news coverage, inability to carry out research, development and commercialization plans, loss or retirement of key executives and research scientists, changes in interest rates, inflationary factors, and other specific risks. In addition, other factors that could cause actual results to differ materially are discussed in the Company's most recent Form 10-QSB and Form 10-KSB filings with the Securities and Exchange Commission.

Contact:

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