HEPALIFE TECHNOLOGIES INC
Form 8-K
March 31, 2005

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

March 23, 2005

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 March 23, 2005, HepaLife Technologies, Inc. issued a news release to reiterate its previously forecasted expectations of increased drug induced liver injuries, in response to the record number of adverse-events filed with the FDA, according to findings published by USA Today. This news release, dated March 23, 2005, 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 March 23, 2005

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: March 31, 2005

EXHIBIT 99.1

Drug Complaints Reach Record High at US Food & Drug Administration; HepaLife Reiterates Expected Rise in Drug-Induced Liver Injury.

USA Today reveals over 422,500 adverse-events filed with the FDA - an increase of nearly 14% from previous year. Earlier CDC report finds almost half of all Americans now using prescription drugs.

Vancouver, BC March 23, 2005 HepaLife Technologies, Inc. (OTCBB: HPLF), a development stage biotechnology company focused on the identification, development and eventual commercialization of technologies and products for liver toxicity detection and the treatment of various forms of liver dysfunction and disease, today reiterated its previously forecasted expectations of increased drug induced liver injuries, in response to the record number of adverse-events filed with the FDA, according to findings published by USA Today.

In a March 14, 2005 article *(Drug Complaints Reach Record High)*, USA Today states: Drug side effects and other related health problems reported to the Food and Drug Administration reached an all-time high in 2004 and culminated with over 422,500 adverse-event reports, an increase of nearly 14% from the previous year.

It s disturbing to see the number of adverse drug reactions rising so dramatically, although frankly, this phenomenon isn t entirely unexpected, commented Mr. Harmel S. Rayat, Chairman of HepaLife.

After all, only three months earlier, we learned through the Centers for Disease Control that almost half of all Americans are now taking at least one prescription drug and one person in every six is taking three or more. At that time, I announced our assertion that drug related liver injury and adverse effects would rise as a consequence of greater prescription drug usage this report certainly supports our expectations, explained Mr. Rayat.

(HepaLife s December 15, 2004 press release can be viewed at:

http://www.hepalife.com/Investor/PressReleases/20041215-1.html)

Echoing similar sentiment, USA Today quotes Paul Seligman, director of the FDA s Office of Pharmacoepidemiology and Statistical Sciences: There are more drugs on the market and more use of pharmaceuticals in general. Clearly, when you have more products on the market, you re likely to have more side effects.

It s particularly important to note however, stated Mr. Harmel Rayat, that even though the number of reports filed with the FDA is greater than ever before, industry analysts believe these incidents remain generally under-reported.

According to USA Today, the bulk of adverse-event reports are submitted by drug manufacturers in accordance with FDA requirements to file such details relating to use of their products. However, physicians, nurses and patients are not required to file - instead, their participation is entirely voluntary. As a result, states the USA Today article, annual totals are believed to cover only a percentage of the actual number of serious drug reactions and problems.

Among known adverse-effects, drug-induced liver damage (hepatotoxicity) is ranked as one of the most serious complications from pharmaceutical compounds. Drug toxicity to the liver is the most common cause for withdrawal of approved medications, and drug-induced liver disease remains the leading cause of acute liver failure in America.

NIH: Drug and Tox-Induced Liver Disease is the Leading Cause of Acute Liver Failure

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

According to a subsection of the report (Drug and Tox-Induced Liver Disease; Chapter 8), Hepatotoxicity now represents the leading cause of acute liver failure, and is the most common reason for withdrawal of an approved medication from clinical use.

The NIH report further states that, drug induced liver injury accounts for over half of acute liver failure cases in the United States, and proposes specific research goals to help deal with the problem. The report explains that the first objective is: To develop animal models or in vitro systems for the study of different forms of idiosyncratic drug-induced liver injury, both allergic and non-allergic.

These in vitro testing technologies are critical to ensuring the industry s success in the battle against drug-induced liver toxicity, and NIH support for development of such platforms is particularly timely for HepaLife explained Mr. Rayat. In the past few weeks, we ve announced specific initiatives to expand our research efforts in this area, and develop novel in vitro testing technologies using the PICM-19 cell line - patented, proprietary cells with unique, liver-like traits.

(HepaLife s February 22, 2005 press release can be viewed at:

http://www.hepalife.com/Investor/PressReleases/20050222-1.html)

In addition to its potential application for pre-screening toxins in pharmaceutical and chemical compounds, the PICM-19 cell line is currently being optimized and tested by HepaLife for eventual use and integration into the first-ever, artificial liver device of its kind a potentially life-saving solution for patients dying from liver failure.

According to the NIH: In the area of acute liver failure, the primary goals of research should be in developing means to prevent acute liver failure and ameliorate its course Most helpful would be an artificial or bioartificial liver assist device that could be used to sustain patients and serve as a bridge to liver transplantation, which is the only effective treatment that is currently available for fulminant hepatic failure.

As reported in HepaLife s press release dated December 8, 2004, results from ongoing research into its proprietary embryonic liver stem cell line, PICM-19H, have surpassed initial expectations. Notably, these cells recorded higher growth density than their parent cell line, while determinations of inducible P-450, ammonia removal, and urea

production similarly yielded markedly positive results, all highly beneficial attributes towards the development of a bio-artificial liver device for use by human patients suffering from liver disease.

In response to the growing number of 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.

ABOUT HEPALIFE TECHNOLOGIES, INC.

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

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

Artificial Liver Device

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.

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

For additional information, please visit www.hepalife.com

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

To view the full HTML text of this release, please visit

http://www.hepalife.com/Investor/PressReleases/20050323-1.html

Legal Notice Regarding Forward-Looking Statements

No statement herein should be considered an offer or a solicitation of an offer for the purchase or sale of any securities. 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. We currently have no products intended to diagnose, treat, prevent or cure any disease. The statements contained in this press release regarding our on going research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration. There can be no assurance that further research and development, and /or whether clinical trial results, if any, will validate and support the results of our preliminary research and studies. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that HepaLife will be able to develop commercially viable products on the basis of its technologies. 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. The Company undertakes no obligation to publicly release the results of any revisions to these forward looking statements that may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

HepaLife Technologies, Inc.

Ms. Laura Rivers-Bowerman, Shareholder Communications

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