HEPALIFE TECHNOLOGIES INC
Form 8-K
February 25, 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

February 22, 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 February 22, 2005, HepaLife Technologies, Inc. issued a news release to announce the addition of research scientist and toxicologist, Mr. Ryan R. Willard. This news release, dated February 22, 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 February 22, 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: February 25, 2005

EXHIBIT 99.1

HepaLife Announces Addition of Toxicology Scientist, to Develop Testing Platform for Liver Toxicity - the Leading Cause of Drug Withdrawals from Clinical Use.

NIH report: identifies need for in vitro testing systems in response to drug-induced liver damage; cites artificial liver device as most helpful for acute liver failure patients.

Vancouver, BC February 22, 2005 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 announced the addition of research scientist and toxicologist, Mr. Ryan R. Willard.

Mr. Willard will lead ongoing research efforts and commercial development of HepaLife s proprietary hepatotoxicity assay system using the patented PICM-19 liver stem cell line. These in vitro toxicological and pre-clinical drug

testing platforms will seek to more accurately determine the potential toxicity and metabolism of new pharmacological compounds in the liver.

Having completed his B.S. degree (cum laude) in Integrated Science and Technology/Biotechnology (ISAT) with a minor in Business at James Madison University in Harrison, VA, Mr. Ryan Willard subsequently undertook studies at the Department of Biology, University of Virginia (Charlottesville, VA).

Among his broad scope of research experience, Mr. Willard has worked on genetic cloning and sequencing, protein purification, and the development of non-isotopic assays.

Most recently, Mr. Willard s efforts as Senior Laboratory and Research Specialist at University of Virginia have focused on the development of a high-throughput assay for screening HIV anti-Rev compounds, testing positive compounds from the screen for efficacy and toxicity, and ultimately working towards elucidating a mechanism for each.

We look forward to leveraging Mr. Willard s wide range of scientific knowledge, but more specifically, his particular expertise in assay development and testing of compounds on cell lines skill sets I believe will help our ongoing efforts to develop proprietary technology for detecting and testing compounds for their toxic effects on the liver, commented Mr. Arian Soheili, President of HepaLife.

With heightened public concern and raised awareness of the critical need to address liver toxicity, the addition of Mr. Willard to HepaLife s efforts in this area, is particularly timely. Recently, worldwide media coverage of side-effects from pharmaceutical drugs, and the government s first-ever, large scale, NIH initiative to address liver disease have alerted the public to the liver injury and death caused by drug toxicity. continued Mr. Soheili.

National Institutes of Health Issues Action Plan on Liver Disease

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

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 explains 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; with the first stated objective being: 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.

For us, it is particularly encouraging to see the NIH formally advocate development of in vitro testing technologies in order to address liver toxicity this is precisely the mechanism HepaLife is developing using the PICM-19 cell line. explained HepaLife President, Mr. Arian Soheili.

Mr. Soheili continued, We re further bolstered by the fact that this same NIH report has also clearly addressed the immediate and absolute need for an artificial liver device for patients suffering from acute liver failure and chronic liver disease we have actively pursued development of such a device and have long believed it to be an entirely critical, life-saving solution for patients dying from liver failure.

According to the NIH report, 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 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

To view the full HTML text of this release, please visit http://www.hepalife.com/Investor/PressReleases/20050222-1.html

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.

HepaLife Technologies, Inc.

Ms. Laura Rivers-Bowerman, Shareholder Communications

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