HEPALIFE TECHNOLOGIES INC
Form 8-K
February 11, 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 2, 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 (see General Instruction A.2. below):

[ ] 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 2, 2005, HepaLife Technologies, Inc. issued a news release to announce plans to expand its scientific research team in order to further bolster the Company s ongoing development of the first-of-its-kind artificial liver device, and its proprietary in vitro toxicology and pre-clinical drug testing platforms. This news release, dated February 2, 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 2, 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 8, 2005

EXHIBIT 99.1

HepaLife to Expand Research Team

Vancouver, BC February 2, 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 plans to expand its scientific research team in order to further bolster the Company s ongoing development of the first-of-its-kind artificial liver device, and its proprietary in vitro toxicology and pre-clinical drug testing platforms.

As a result of evolving scientific events and HepaLife s ensuing initiative to progress its science at an accelerated pace, the Company announced plans to expand its research team with the appointment of additional bioengineering and toxicology staff, who will focus their efforts on specific application and further optimization of HepaLife s proprietary embryonic liver stem cell line, PICM-19H and its associated lineage.

We ve been fortunate to see encouraging outcomes from PICM-19 related research to-date, explained Mr. Arian Soheili, President of HepaLife Technologies, Inc. Now, we believe its time to fully capitalize on these results and to proactively expedite our efforts in two keys areas further development and testing of an experimental bioreactor unit that will be the prototype of a bio-artificial liver device, and timely advancement of our toxicology related science.

Recently, HepaLife s results from research into PICM-19H surpassed Management s initial expectations. Notably, these cells recorded growth of 2-3 times the density of 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.

Additionally, 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.

The incidence of drug-induced liver injury from such compounds is expected to continue rising as a consequence of rampant pharmaceutical drug use and over-medication today, almost half of all Americans take at least one prescription drug and one person in every six takes three or more (Centers for Disease Control and Prevention, December 2004).

With adverse drug reactions now ranked among the ten most common causes of death in the nation, we are determined to rapidly advance our science as judiciously as possible, stated Mr. Soheili. And, for those 25 million Americans suffering with liver disease, the positive, potential implications of our research cannot be overstated. Of critical urgency however, is the development of our artificial liver device for the tens of thousands worldwide who die each year as a consequence of acute liver failure.

An estimated one quarter of Americans will suffer from liver or biliary disease at some point in their lifetime, according to the National Institutes of Health (NIH). As a consequence, last month the 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.

In a subsection of the Action Plan (Complications of Liver Disease; Prevention of Acute Liver Failure) the NIH report states: 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.

Commenting on the NIH Action Plan, Mr. Soheili stated, HepaLife has been working on developing the first-of-its kind artificial liver device for some time now. It is deeply encouraging to know that one of the world s foremost medical research centers, the NIH, concurs with our long-standing research conviction for patients suffering from acute liver failure and chronic liver disease, there is an immediate and absolute need for an artificial liver device. It is my sincere hope that one day, our progressive research and hard work will deliver this critical, life-saving treatment to those liver disease patients who need it most.

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.

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.

HepaLife Technologies, Inc.

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