HEPALIFE TECHNOLOGIES INC
Form 8-K
May 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

May 24, 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 May 24, 2005, HepaLife Technologies, Inc. issued a news release to announce the addition of Dr. Darryl J. Fleishman to the Company s Scientific Advisory Board. This news release, dated May 24, 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 May 24, 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: May 31, 2005

EXHIBIT 99.1

Emergency Medicine Specialist at Front Lines of Adverse Drug Reactions & Acute Liver Failure Joins HepaLife to Assist Ongoing Development of Artificial Liver Device & Hepatotoxicity Testing Platform.

Vancouver, BC May 24, 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 announced the addition of Dr. Darryl J. Fleishman to the Company s Scientific Advisory Board.

Dr. Fleishman brings over a decade of direct medical experience with emergency-room patients suffering from liver disease and acute liver failure as well as those injured by adverse drug effects to the liver.

Drug-induced liver damage, also known as hepatotoxicity, has become increasingly frequent and is now the leading cause of acute liver failure in the United States (National Institute of Diabetes and Digestive Kidney Diseases).

According to the National Institutes of Health, up to 5% of the nation s 100 million-plus hospital admissions can be attributed to adverse drug reactions. Each year, approximately 1.5 million Americans are hospitalized due to adverse drug reactions according to a long-standing study published in the Journal of American Medical Association (JAMA), and an additional 770,000-plus develop drug reactions once they are hospitalized.

In all, over 2.2 million Americans per year more than 6,000 patients each day - suffer adverse drug reactions in hospitals. Sadly, nearly 80,000 children are admitted to hospitals as a consequence of such adverse drug reactions with almost 40% of such cases classified as life-threatening .

Emergency Medicine Specialist Joins HepaLife Scientific Advisory Board

A Board Certified Emergency Medicine Specialist, Dr. Darryl J. Fleishman is a graduate of Boston University School of Medicine (BUSM), established in 1848 and today ranked among America s top five largest independent universities. With over 1,000 clinical trials and 575 funded research programs, BUSM is a distinct leader in clinical medical research.

Having completed his Emergency Medicine Residency Program at Wayne State University in Detroit, Michigan, Dr. Fleishman is currently in active emergency-medicine practice at Illinois St. Francis Hospital & Health Center, established 100 years ago and notably reputed as the state s only hospital of its kind to be ranked among America s top 100 cardiovascular hospitals five times.

Among numerous appointments at Level 1 trauma centers and emergency treatment centers, Dr. Fleishman has tenured at several of Greater Chicago s most respected healthcare institutions, including: Advocate Christ Medical Center, Mt. Sinai Hospital, Holy Cross Hospital, Ingalls Memorial Hospital, and others.

As our research team continues to advance the critical science behind our proprietary artificial liver device and toxicology testing platforms, it is increasingly important for us to leverage the kind of hands-on experience and end-user insight that Dr. Fleishman brings to our Scientific Advisory Board, especially with his years of experience in dealing with liver damage, its side effects and related symptoms in an emergency room setting, commented HepaLife Chairman, Mr. Harmel Rayat.

I m honored to accept this appointment and join the HepaLife team in its fight against liver disease, especially through development of the Company s artificial liver device which I hope will someday be able to help the thousands of Americans awaiting transplants and suffering with the consequences of liver failure, stated Dr. Darryl Fleishman.

Recently, I had the opportunity to visit the research labs in Maryland and see first-hand how HepaLife s research team is making inroads in this area, continued Dr. Fleishman. It s particularly exciting to see the potential implications of the Company s PICM-19H cells for use in toxicity testing.

The need to more efficiently, accurately and cost-effectively pre-screen drugs and chemical compounds for toxicity to the liver cannot be overstated. A toxicity testing platform of this kind may well help reduce the number of patients our hospitals treat for drug-induced liver damage, especially in light of America s increasing use of pharmaceutical products and rising reliance on everyday drugs.

Surprisingly, the most commonly cited pharmaceutical agent responsible for drug-induced liver damage is acetaminophen, implicated in nearly 50% of all acute liver failure in America and ranked as the most frequently administered class of drug during emergency room visits.

Acetaminophen is found in more than 100 products and is the most widely used pharmaceutical analgesic and antipyretic agent, worldwide. As one of the most common pharmaceuticals associated with both intentional and accidental poisoning, acetaminophen related liver toxicity is the leading cause of hepatic failure requiring liver transplantation in Great Britain and the second most common cause of liver failure requiring transplantation in the United States.

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.

Most recently, as reported in the Company s April 11, 2005 press release, HepaLife successfully surpassed it s primary research objectives related to the optimization of the PICM-19H cell line. (HepaLife's April 11, 2005 press release can be viewed at:

http://www.hepalife.com/Investor/PressReleases/20050411-1.html)

To-date, the overall objective of HepaLife s collaborative research work has been, and continues to be, the optimization of culture conditions for the Company s proprietary PICM-19H cell line; such optimization will enable these cells to grow faster, reach higher densities and have optimal function of key liver metabolic and detoxification enzyme systems.

Successful research outcomes will result in incorporation of the PICM-19H cells in an artificial liver device, as well as use in in-vitro toxicology and pre-clinical drug testing platforms. Concurrent with these efforts, bioengineering investigations on the cell culture hardware of HepaLife s artificial liver device are also actively underway.

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 our ongoing research and development and the results attained by us 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/20050524-1.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 commercial 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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