HEPALIFE TECHNOLOGIES INC
Form 8-K
August 16, 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

August 9, 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)

ITEM 1. Changes in Control of Registrant.

None.

ITEM 2. Acquisition or Disposition of Assets.

None.

ITEM 3. Bankruptcy or Receivership.

None.

ITEM 4. Changes in Registrant s Certifying Accountant.

None.

ITEM 5. Other Events.

None.

ITEM 6. Resignations of Registrant s Director s

None.

ITEM 7. Financial Statements and Exhibits.

The following exhibit is filed herewith:

Exhibit Number

Description

99.1

Press Release dated August 9, 2004, issued by HepaLife Technologies, Inc.

ITEM 8. Change in Fiscal Year.

None.

ITEM 9. Regulation FD Disclosure

Cautionary Statement Pursuant to Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995:

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 9 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 August 9, 2004, HepaLife Technologies, Inc. issued a news release to announce the addition of Dr. Michael Ott to the Company s Scientific Advisory Board. This news release, dated August 9, 2004, is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

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/ Harmel S. Rayat

Harmel S. Rayat

Secretary/Treasurer, Director

Date: August 16, 2004

EXHIBIT 99.1

Professor Dr. med. Michael Ott Joins HepaLife Scientific Advisory Board

Associate Professor of Experimental Hepatology at Leading Liver Transplant University-Hospital to Guide Ongoing Research, Development, and Commercialization of HepaLife s Proprietary, Cell-Driven Technologies

Vancouver, BC August 9, 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 announced the addition of Dr. Michael Ott to the Company s Scientific Advisory Board.

Dr. Michael Ott is Associate Professor for Experimental Hepatology at the Hannover Medical School, recognized worldwide as one of the leading centers for transplantation medicine.

Dr. Ott holds both MD and doctoral degrees from one of Germany s largest and most prestigious medical training schools, Westfälische-Wilhelms-University (Munster), first established in 1588 and today associated with the Max-Planck-Institute, one of the world s foremost scientific research institutions.

As an authority in experimental hepatology (the study of liver function and disease) and highly-innovative liver cell transplantation procedures for human patients suffering from acute liver failure, Dr. Michael Ott brings unique expertise to HepaLife in the areas of adult and embryonic stem cell research as well as gene expression in fetal liver and hepatic progenitor cells.

Dr. Michael Ott Breakthrough Liver Research

With experience in molecular biology at the Pathophysiology Laboratory for Hemostasis and Microcirculation at the University of Muenster, Dr. Ott undertook internal medicine training at the Johann-Wolfgang-Goethe University Medical Center in Frankfurt. He subsequently commenced research efforts at the Marion Bessin Liver Research Center at the Albert Einstein College of Medicine (New York) under the guidance of Dr. Sanjeev Gupta, a leading

expert on liver physiology, hepatocyte transplantation and hepatic gene transfer.

Over a span of 15 years, Dr. Michael Ott s work in basic and clinical research in gastroenterology and hepatology has been extensively published in both abstract and peer-reviewed journals such as the Journal of Biological Chemistry, Hepatology, American Journal of Pathology, Journal of Hepatology, Differentiation and the International Journal Developmental Biology.

The translation of Dr. Ott s basic research protocols for cell transplantation into clinical protocols has led to the first-ever application of human hepatocytes for the treatment of liver diseases in Germany.

In collaboration with his highly-innovative research team, Dr. Ott continues to investigate the effects of hepatic cell transplantations in various liver diseases in animal models and is developing strategies to improve regeneration of chronically diseased liver tissue.

Dr. Ott has also developed techniques for the isolation, characterisation and cryopreservation of human hepatocytes for clinical use according to the guidelines of good manufacturing practice and continues to pursue additional clinical research for the management of acute liver failure and the application of extracorporeal liver devices in patients with severe liver disease.

Dr. Ott s addition to our Scientific Advisory Board comes at a very exciting time in HepaLife s evolution, especially in light of his extensive knowledge in basic research, translational medicine and pharmaceutical production of cell products for clinical applications, explained Mr. Arian Soheili, President of HepaLife.

Most importantly, Dr. Ott s international reputation with leading experimental liver science technologies and surgical procedures dovetails very well with the successful track-records of Mr. Frank Menzler and John Bergmann; all three gentlemen have skillfully transitioned bench research into viable therapeutic, regenerative, and surgical applications.

John Bergmann & Frank Menzler Distinguished Scientific Advisory Board Members

Dr. Ott joins Mr. John Bergmann, currently serving as a Distinguished Member of the HepaLife Scientific Advisory Board, and Senior Research Associate and Laboratory Manager with the Department of Human Biological Chemistry and Genetics at the University of Texas Medical Branch.

Notably, Mr. Bergmann's most current UTMB research has been in collaboration with Chrysalis BioTechnology, Inc., a biopharmaceutical company recently acquired by OrthoLogic Corporation (Nasdaq:OLGC), and actively developing Chyrsalin(r) related tissue repair, chronic wound healing, and vascular repair products.

Chyrsalin(r), also known as TP508, is a synthetically manufactured peptide which represents a portion of the human enzyme, thrombin -- a naturally occurring molecule in the body that is responsible for blood clotting and initiates many of the cellular events responsible for tissue repair.

With 30 years of scientific research experience and a Master s degree in Biology (Montclair State University), Mr. Bergmann s work has been extensively published in both abstract and peer-reviewed journals such as the Journal of Clinical Microbiology, Journal of Environmental Science and Health, Journal of Cell Biochemistry, American Journal of Physiology, Journal of Cell Biology and others.

Also, serving on the HepaLife Scientific Advisory Board is Mr. Frank Menzler, previously Marketing Manager at the global medical device leader, Guidant Corporation s (NYSE: GDT) Cardiac Surgery Business Unit in Brussels, Belgium.

Prior to joining Guidant, Mr. Menzler co-founded Impella Cardiotechnik AG (Germany), one of the nation s first-ever academically-sponsored research efforts to successfully receive private venture capital funding.

Impella - a medtech start up venture - grew to 90 employees, designing, developing, and ultimately commercializing minimally-invasive cardiac assist systems for use in cardiology and cardiac surgery.

Today, Impella manufactures and markets intracorporeal micro blood pumps with technology protected by more than 30 European and international patents. In 2000, the Company was honored with innovation awards by the City of Aachen and German Commerce and was added to the list of the World s 40 Leading Technology Pioneers in February 2003 by the Davos World Economic Forum as one of only two German companies to reach this milestone.

Mr. Menzler holds a Master s degree in Business Administration (MBA) from Northwestern University s, Kellogg School of Business and a Diplom-Ingenieur (Master s of Science equivalent) in Mechanical and Biomedical Engineering from RWTH Aachen, Germany s largest university of technology and one of Europe s leading technology institutions, renowned for its standards of education and research excellence since 1870.

About HepaLife Technologies, Inc.

HepaLife Technologies, Inc. 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.

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.

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.

Angela Stecca, Investor Relations

Phone: (800) 518-4879

Web Site: www.HepaLife.com