HEPALIFE TECHNOLOGIES INC
Form 8-K
August 04, 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 4, 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 2, 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 2, 2004, HepaLife Technologies, Inc. issued a news release to announce the recent addition of Dr. Ayesha Mahmood, who will lead ongoing research and development work on the patented application of the PICM-19 liver stem cell line to an artificial liver device for the treatment of human patients with liver failure. This news release, dated August 2, 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 4, 2004

EXHIBIT 99.1

Dr. Ayesha Mahmood Joins Research Team

VANCOUVER, British Columbia, August 2, 2004 (PRIMEZONE via COMTEX) -- 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 recent addition of Dr. Ayesha Mahmood.

Dr. Mahmood will lead ongoing research and development work on the patented application of the PICM-19 liver stem cell line to an artificial liver device for the treatment of human patients with liver failure.

Dr. Ayesha Mahmood holds a Bachelor's degree in Biochemistry, a Master of Science in Chemical Engineering and a PhD in Biomedical Engineering from Wayne State University (WSU), a biomedical engineering pioneer since 1939 and a recognized research innovator in small diameter blood vessel grafts, tissue engineering and biomaterials for tissue and organ replacement.

We re proud to have Dr. Mahmood join us, stated Mr. Arian Soheili, President of HepaLife Technologies. Dr. Mahmood s solid expertise in bioreactor design, construction and testing, alongside her considerable proficiency with cell culture and growth kinetics are precisely the unique skills our project now requires.

Dr. Mahmood brings expertise from America s largest single-campus medical training institution, boasting over half a century of highly regarded biomedical innovation with such breakthroughs as the world s first successful open heart surgery and the first ever application of a mechanical heart, continued Mr. Soheili. I look forward to HepaLife fully leveraging her inventive engineering spirit.

Dr. Mahmood has published studies and delivered research presentations on biomaterials engineering, tissue engineering, chemical engineering and more, and has presented her findings to leading scientific peer review groups, including the Transactions of the Society for Biomaterials, American Institute of Chemical Engineers, Society of Biomaterials, and others.

Working under the auspices of Dr. Neil C. Talbot and Dr. Thomas J. Caperna, co-inventors of the PICM-19 liver stem cell line and its patented application to an artificial liver device, Dr. Mahmood will conduct ongoing research and development work at two USDA laboratories, the Growth Biology Laboratory and the Biotechnology and Germplasm Laboratory, both located in Beltsville, Maryland.

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.

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.

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.

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