HEPALIFE TECHNOLOGIES INC
Form 8-K
May 14, 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

May 14, 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 May 14, 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 May 14, 2004, HepaLife Technologies, Inc. issued a news release to announce its plans for the development of liver cell specific in vitro toxicology and pre-clinical drug testing platforms. The in vitro platforms will be based on the patented PICM-19 pig liver stem cell line which is currently being tested by the Company for use in an artificial liver device. This news release, dated May 14, 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: May 14, 2004

EXHIBIT 99.1

HepaLife expands into developing technology for hepatotoxicity, the most common reason cited for the withdrawal of an approved drug, pre-clinical drug failures, and for refusal of drug approval by the FDA.

Vancouver, BC May 14, 2004 - - HepaLife Technologies, Inc. (OTCBB: HPLF), a development stage biotechnology company focused on technologies and products to treat various forms of liver dysfunction and disease, is pleased to announce its plans for the development of liver cell specific in vitro toxicology and pre-clinical drug testing platforms. The in vitro platforms will be based on the patented PICM-19 pig liver stem cell line which is currently being tested by the Company for use in an artificial liver device.

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.

Resulting in part from the limitations of current testing methodology, safety problems are often discovered only during clinical trials, and unfortunately, sometimes after marketing. Examples of recent post-market discoveries include Accolate (asthma drug), Duract (analgesic and anesthetic) and Rezulin (diabetes), all of which were linked to liver damage.

Hepatocytes, the major cell type comprising the liver, perform the important task of metabolizing or detoxifying drug compounds that enter the body. This is accomplished primarily through cytochrome P450 enzymes that are abundantly expressed in hepatocytes. Therefore, hepatocytes grown out of the body in culture dishes (in vitro), have application for the rapid screening of multiple drug candidates to predict their potential liver toxicity and liver-specific pharmacological characteristics prior to clinical testing.

The patented PICM-19 liver stem cell line, whose cells can differentiate into either hepatocytes or bile duct cells (another key cell type of the liver) are currently being tested for use in an artificial liver device by HepaLife Technologies. 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. Alternatively, the PICM-19 cells can be induced to form functional liver bile ductules in vitro. As a result, HepaLife, using the patented PICM-19 cell line, plans to develop 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, and that will be specifically targeted to either hepatocytes or bile duct cells.

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 to treat various forms of liver dysfunction and disease.

Presently, through a Cooperative Research and Development Agreement, HepaLife Technologies is working towards optimizing the hepatic functionality of a patented cell line, whose hepatic characteristics have been demonstrated to have potential application in the production of an artificial liver device for use by human patients with liver failure, as well as in vitro toxicology testing to more accurately determine the potential toxicity and metabolism of new pharmacological compounds.

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, and for improved assays for liver toxicity testing and the development of liver disease drug therapies.

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.

Contact:

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