HEPALIFE TECHNOLOGIES INC Form 8-K January 08, 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

January 7, 2004

Date of Report (Date of earliest event reported)

HEPALIFE TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

<u>Florida</u>

<u>000-29819</u>

<u>58-2349413</u>

(State or other jurisdiction of incorporation)

(Commission File Number) (I.R.S Employer Identification No.)

1628 West 1st Avenue, Suite 216, Vancouver, British Columbia, V6J 1G1

(Address of principal executive offices)

<u>(800) 518-4879</u>

(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 January 7th, 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

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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 January 7th, 2004, HepaLife Technologies, Inc. issued a news release to announce the initial results of its first phase of research towards the development of a bio-artificial liver device for use by human patients with liver failure. This news release, dated January 7th, 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: January 7th, 2004

EXHIBIT 99.1

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<u>Improved cell line</u> developed yielding 2-3 times cell density; <u>Positive research results</u> obtained from key enzyme systems; <u>Development and testing of bioreactor device now begins</u>.

Vancouver, BC January 7, 2004 - - HepaLife Technologies, Inc. (OTCBB: HPLF) is pleased to announce the initial results of its first phase of research towards the development of a bio-artificial liver device for use by human patients with liver failure.

Beginning in June 2003, research and testing has been conducted to observe cell growth and assess specific hepatic functions of the patented PICM-19 cell line and of PICM-19P, a subpopulation of the original PICM-19 cell line. PICM-19P has been in continuous culture for over one year without showing any detectable changes in hepatocyte morphology and function.

The PICM-19P cells grow to 2-3 times the cell density of the original PICM-19 cell line and are therefore attractive for use in a bio-artificial liver device. In addition to measuring cell growth and densities, determinations of inducible P-450 and urea production were conducted and have yielded positive results.

Since the liver is primarily responsible for detoxifying many substances, the positive P-450 tests are of particular importance because this enzyme system is a key component in the overall hepatic detoxification pathway of drugs and other xenobiotics. Additionally, ureagenesis is another important hepatic function since urea production is required for the detoxification of ammonia derived from catabolism of a number of nitrogen containing compounds.

Further research is ongoing, including the immediate development of a bioreactor device, an early stage prototype of a bio-artificial liver device into which cells from the PICM-19P cell line will be seeded and further tested for growth and hepatic function during the first half of 2004.

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.

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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.

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 that a strong need exists for an artificial liver device, now and into the foreseeable future.

For additional information, please visit <u>www.hepalife.com</u>.

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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