HEPALIFE TECHNOLOGIES INC Form 8-K July 21, 2003

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

July 21st, 2003

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)

(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 NumberDescription99.1Press Release dated July 21st, 2003, 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 July 21st, 2003, HepaLife Technologies, Inc. issued a news release announcing that through a Cooperative Research and Development Agreement (CRADA) with the USDA s Agricultural Research Service, the primary tool linking government and industry researchers, HepaLife Technologies, Inc. is collaborating towards optimizing the hepatic functions 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.

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/ Jeet Sidhu

Jeet Sidhu

Director

Date: July 21st, 2003

25 MILLION AMERICANS AFFLICTED WITH LIVER DISEASE

Vancouver, BC July 21, 2003 - - Presently, through a Cooperative Research and Development Agreement (CRADA) with the USDA s Agricultural Research Service, the primary tool linking government and industry researchers, HepaLife Technologies, Inc. (OTCBB: HPLF) is collaborating towards optimizing the hepatic functions 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.

Liver Transplants

For people with severe liver failure, orthotopic liver transplantation is the only effective treatment therapy and is now an estimated \$1.5 billion business. At present, there are upwards of 17,000 adults and children medically approved and waiting for liver transplants in the U.S., which, at approximately \$300,000 per transplant, would increase the potential size of the liver transplant market to over \$5 billion if enough donor organs were available.

Unfortunately, there are just over 5,000 livers available for transplant annually. Due to a severe shortage of organ donors, the waiting time for potential liver recipients could be as long as two to three years, with 20-30% of these patients not surviving the wait period.

For those who receive liver transplants, some 31% will die within 5 years, while the rest will endure a life time of immunosuppressive drugs, rendering them susceptible to life threatening infections such as kidney failure and increased risk of cancer, and follow up costs of \$25,000 per year to the health care system.

Sadly, patients suffering from advanced liver failure who are either not whole organ transplant candidates or who cannot find an available organ in a timely fashion have limited prospects for survival.

Liver Disease

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According to the American Liver Foundation, 1 in every 11, or approximately 25 million Americans are afflicted with liver disease. During 2000 alone, 26,552 people died in the United States as a consequence of cirrhosis and chronic liver disease (National Vital Statistics Report, September 16, 2002).

In purely economic terms, liver-related problems cost society over \$10 billion per year. In human terms, the costs cannot be calculated.

Each year, hundreds of thousands of individuals worldwide experience acute or chronic liver failure caused by hepatitis and other infections, degenerative diseases, trauma, drug overdoses and alcohol abuse. The last of these, alcohol abuse, is a major cause of liver disease in America today.

Of the nearly 14 million Americans (1 in every 20) that either abuse alcohol or are alcoholics (National Institute on Alcohol Abuse and Alcoholism), 10 to 20 percent will develop cirrhosis of the liver, one of the leading causes of death among young and middle-age adults in the US. Individuals with cirrhosis are particularly prone to developing fatal bacterial infections, kidney malfunctions, stomach ulcers, gallstones and cancer of the liver.

<u>Hepatitis</u>

According to the Centers for Disease Control, between 15-25% (upwards of 312,500 Americans) of the estimated 1.25 million chronically infected hepatitis B sufferers will die from chronic liver disease. Globally, an estimated 300 million people are infected with hepatitis B, causing approximately 1,000,000 deaths per year.

Various studies, when combined together, suggest that over 200 million people around the world are infected with hepatitis C. Statistically, as many people are infected with hepatitis C as are with HIV, the virus that causes AIDS. Without large scale efforts to contain the spread of hepatitis C and treat infected populations, the death rate from hepatitis C will soon surpass that of AIDS.

Of the estimated 4.5 million Americans infected with hepatitis C, for which there is no cure, an estimated 70-80% will develop chronic liver disease and 20% will die. The annual health care costs for the affected U.S. population with chronic hepatitis C has been estimated to be as high as \$9 billion, compared to annual cost of \$360 million for hepatitis B sufferers.

In addition to alcohol abuse, drug overdoses and hepatitis, other causes of liver disease include primary biliary cirrhosis, hemochromatosis, Wilson s disease, alpha1-antitrypsin deficiency, glycogen storage disease, autoimmune hepatitis, cardiac cirrhosis and schistosomiasis. In total, according to the American Liver Foundation, approximately 25 million Americans are afflicted with liver disease.

Artificial Liver Device

The need for an artificial liver device able to remove toxins and improve immediate and long-term survival rates for patients suffering from liver disease 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.

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 (CRADA) with the USDA s Agricultural Research Service, the primary tool linking government and industry researchers, HepaLife Technologies is collaborating towards optimizing the hepatic functions 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.

The CRADA program, authorized under the Federal Technology Transfer Act of 1986, allows federal laboratories and businesses to form partnerships that help move new technologies to the marketplace and allows the collaborating company the first right to negotiate an exclusive license to inventions emerging under the agreement.

Dr. Neil C. Talbot (cell biologist), Dr. Thomas J. Caperna (biochemist), and Dr. Mark Saarinen (bioengineer) are spearheading the Company s collaborative research initiative at two laboratories, the Growth Biology Laboratory and the Biotechnology and Germplasm Laboratory, both located in Beltsville, Maryland.

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

Legal Notice Regarding Forward-Looking Statements

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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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