HEPALIFE TECHNOLOGIES INC
Form 8-K
April 14, 2005

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

April 11, 2005

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

SECTION 1. Registrant's Business and Operations

None.

SECTION 2. Financial Information

None.

SECTION 3. Securities and Trading Markets

None.

SECTION 4. Matters Related to Accountants and Financial Statements

None.

SECTION 5. Corporate Governance and Management

None.

SECTION 6. [Reserved]

N/A.

SECTION 7. Regulation FD

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 7 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 April 11, 2005, HepaLife Technologies, Inc. issued a news release to announce that several of its previously announced research objectives have been successfully achieved. This news release, dated April 11, 2005, is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

SECTION 8. Other Events

None.

SECTION 9. Financial Statements and Exhibits

The following exhibits are furnished as part of this report:

Exhibit 99.1 Press Release dated April 11, 2005

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/ Arian Soheili

Arian Soheili

President and CEO

Date: April 14, 2005

EXHIBIT 99.1

HepaLife Surpasses Research Objectives:

Continues to Advance Optimization of Proprietary Liver Cell Line for Final Use in Artificial Liver Device.

New experiments to study factors that may extend the time liver cells remain functional at room temperature, potentially improving long distance transport and allowing for faster utilization in clinical or hospital setting.

Vancouver, BC April 11, 2005 HepaLife Technologies, Inc. (OTCBB: HPLF), a development stage biotechnology company focused on the identification, 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 that several of its previously announced research objectives have been successfully achieved.

Along with measuring positive P450 activity, urea production and ammonia clearance from its proprietary PICM-19H liver cell line (currently being studied for eventual use in an artificial liver device by patients suffering from acute liver failure and chronic liver disease), the Company is pleased to announce that its research has successfully demonstrated that PICM-19H cells can be maintained independently of STO feeder cells. In ongoing experimentation, commercially available extracellular matrix material has been found to support PICM-19H cells in long term maintenance culture, an important milestone.

Of particular significance, PICM-19H cell culture without the aid of STO feeder cells would allow for a more defined cell culture system, a research and application goal of the Company. A defined PICM-19H cell culture system (i.e., one free of feeder cells and undefined cell culture medium constituents) may also be important for potential FDA approval of HepaLife s artificial liver device, currently under development and expected to incorporate the PICM-19H cells as a key component.

To-date, the overall objective of HepaLife s collaborative research work has been, and continues to be, the optimization of culture conditions for the Company s proprietary PICM-19H cell line; such optimization will enable these cells to grow faster, reach higher densities and have optimal function of key liver metabolic and detoxification enzyme systems. Successful research outcomes will result in incorporation of the PICM-19H cells in an artificial liver device, as well as use in in-vitro toxicology and pre-clinical drug testing platforms. Concurrent with these efforts, bioengineering investigations on the cell culture hardware of HepaLife s artificial liver device are also actively underway.

Additionally, as a result of positive ongoing scientific developments, the Company s research has been further expanded to include the study of various factors that may improve and extend the length of time that PICM-19H cells can be stored at room temperature instead of heated incubators, designed to artificially mimic body temperature.

Already, the PICM-19H cells remain functional and viable after one week of room temperature storage. However, further extending the storage time in culture at room temperature could allow for easier long distance transportation of these cells. Moreover, the ability to place these cells in suspended animation at room temperature will enable more efficient utilization of HepaLife s artificial liver device in its clinic or hospital setting.

The benefits and cost savings of being able to ship the most important and perishable component of an artificial liver device the cells around the country without special incubator equipment would be tremendous, states Mr. Arian Soheili, President and CEO of HepaLife Technologies, Inc.

Mr. Soheili continues, When it comes to developing a fully functional, therapeutically effective artificial liver device, the key is not in the hardware itself rather, it s the biological component that goes inside.

Our cell line, we believe, is what sets us apart from everyone else! As we progress and surpass each of our research objectives for our proprietary cell line which, to date has performed beyond our expectations - we move closer and closer to making the development of an artificial liver device a reality for the millions of individuals who suffer from liver disease.

Equally important, I consider HepaLife s PICM-19H cell research of particular significance since it directly addresses the widely-held scientific opinion that the greatest hindrance in development of a therapeutically effective artificial liver device has been the lack of an appropriately defined liver cell line, able to provide the functions of an intact liver. Mr. Soheili concludes. Growing (culturing) or maintaining liver cells outside of the body (in vitro), has proven difficult because once liver cells are removed from the body for culture, they soon lose their normal function.

In contrast to HepaLife s PICM-19H, the cellular components of other artificial liver devices being developed to-date, have been based on freshly isolated porcine hepatocytes, cell lines established from human liver tumors, stem-cell-like cells prepared from fresh human adult liver tissue, and human or pig liver cells transformed or immortalized by the addition of oncogenes (i.e., genes associated with cancer) through genetic engineering. While immortalized liver cells retain a high capacity for growth, they often have reduced or altered hepatocyte functions.

Unfortunately, most artificial liver systems being developed at other labs and companies have not lived up to initial expectations as a consequence of problems relating to their inability to grow liver cells quickly and safely, poor cell functionality, and inconsistent results from filtering or dialysis devices.

PICM-19 Cell Line

Unique in its origin, the PICM-19 fetal liver cell line has been isolated from the primary culture and spontaneous differentiation of pig epiblast cells (embryonic stem cells). Also unique are its liver stem cell qualities. The PICM-19 cell line can differentiate into either bile duct cells or hepatocytes, the two cell types that make up 98% of the liver s tissues and perform the vital functions of the liver.

The hepatocyte, or liver cell, comprises most of the liver tissue and is responsible for most of the vital metabolic and detoxification functions of the liver. Tests in mice have shown that the PICM-19 cell line is not tumor-causing, and even after years in continuous culture, the cell line has retained its desirable liver cell properties. The PICM-19 cells grown in vitro, synthesize liver-specific proteins such as albumin and transferrin, and display liver-specific functions such as ureagenesis and cytochrome P450 activity.

As a result, and after further optimization of PICM-19 s in vitro culture, the cell line has the potential for useful application to the creation of an artificial liver device for human patients experiencing liver failure. Also, the PICM-19 cell line may be superior for in-vitro toxicological and pre-clinical drug testing platforms in more accurately

determining the potential toxicity and metabolism of new pharmacological compounds in the human liver. And unique to the PICM-19 cell line, it may prove possible to differentiate drug toxicity specifically targeting either hepatocytes or bile duct cells due to the stem cell characteristics of the cell line.

The PICM-19 cell line is also a good model of bile duct epithelium because of its unique property of forming functional bile ducts in vitro (i.e., in the culture dish). Therefore, the PICM-19 cell line could be useful in the study of bile duct function and pathology such as bile duct pathologies associated with cystic fibrosis.

ABOUT HEPALIFE TECHNOLOGIES, INC.

HepaLife Technologies, Inc. (OTCBB:HPLF) is a development stage biotechnology company focused on the identification, 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.

At present, the Company does not have commercial products intended to diagnose, treat, cure or prevent any disease. The statements contained in this press release regarding our ongoing research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration.

For additional information, please visit www.hepalife.com

To receive future press releases via email, please visit http://www.hepalife.com/Alerts-Index.asp

To view the full HTML text of this release, please visit http://www.hepalife.com/Investor/PressReleases/20050411-1.html

Legal Notice Regarding Forward-Looking Statements

No statement herein should be considered an offer or a solicitation of an offer for the purchase or sale of any securities. 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. We currently have no commercial products intended to diagnose, treat, prevent or cure any disease. The statements contained in this press release regarding our on going research and development and the results attained by us to-date have not been evaluated by the Food and Drug Administration. There can be no assurance that further research and development, and /or whether clinical trial results, if any, will validate and support the results of our preliminary research and studies. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that HepaLife will be able to develop commercially viable products on the basis of its technologies. 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. The Company undertakes no obligation to publicly release the results of any revisions to these forward looking statements that may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

HepaLife Technologies, Inc.

Ms. Laura Rivers-Bowerman, Shareholder Communications

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