Galmed Pharmaceuticals Ltd.
Form 6-K
June 07, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16

Under the Securities Exchange Act of 1934

For the Month of June 2016

001-36345

(Commission File Number)

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

16 Tiomkin St.

Tel Aviv 6578317, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F x Form 40-F ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Attached hereto and incorporated herein by reference is a press release, dated June 7, 2016, and entitled "Galmed Pharmaceuticals Expands its Ongoing Phase IIb ARREST Study to China."

This Form 6-K is incorporated by reference into the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on August 11, 2015 (Registration No. 333-206292) and its Registration Statement on Form F-3 filed with the Securities and Exchange Commission on March 31, 2015 (Registration No. 333-203133).

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, thereunto duly authorized.

Galmed Pharmaceuticals Ltd.

Date: June 7, 2016 By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer

Galmed Pharmaceuticals Expands its Ongoing Phase IIb ARREST Study to China

TEL AVIV, Israel, June 7, 2016 – Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of liver diseases, announced today that it has expanded the clinical operations of its ongoing Phase IIb ARREST study into China and has also commenced a pharmacokinetic ("PK") study in healthy Chinese subjects domiciled in the United States.

The trial investigator in China is Professor George K.K. Lau, who serves as Co-Director of Hepatology at 302 Hospital in Beijing and Director at Humanity and Health Medical Center in Hong Kong. Professor Lau has a distinguished research career and is recognized as an international leader in clinical trials, primarily in the field of chronic hepatitis B virus (HBV) infection and other liver-related diseases. Professor Lau has more than 500 publications in scientific journals, such as the New England Journal of Medicine, Lancet, Gastroenterology, Journal of Hepatology, Hepatology and Blood.

Professor Lau commented, "The significant, and unfortunate, growth rate in personal lifestyle decisions that give rise to NAFLD and NASH in China, and the Far East in general, are worrisome. Over the last 5-10 years, the scientific and medical community in China and beyond have awoken to this reality and concluded that this disease represents a significant unmet need." Professor Lau concluded, "I'm enthusiastic to investigate the effect of Aramchol™ on NASH patients and its seeming ability to hit important molecular targets, and affect change, in this complex disease."

In parallel, Galmed has also initiated a pharmacokinetic ("PK") study in Chinese subjects who are domiciled in the United States, entitled "Pharmacokinetics of Single and Multiple Escalating Doses of Aramchol Administered under Fed Conditions in Healthy Chinese Volunteers." The Company expects to enroll up to 64 subjects in this six-month study, consisting of two parts. In part A, 32 subjects shall receive a single escalating dose; Part B shall enroll 32 subjects which shall receive a multiple escalating dose. Dr. Evelyn Darius will serve as the Study Investigator. If the PK profile from Part A is similar to the existing PK data in non-Chinese subjects, then the study may be stopped prior to enrolling Part B. The results of Part A of the PK study are expected to be available in August 2016.

Allen Baharaff, Galmed’s President and Chief Executive Officer stated, "With an increasing obesity and diabetes epidemic in the Chinese population, in proportions similar to the Western world, we believe China is likely to experience an increasing outbreak of NASH and NAFLD patients.”

New epidemiology data recently presented at the 3rd Chinternational Hepatology Symposium (CIHS) in Beijing indicate that NAFLD could replace viral hepatitis as the leading cause of chronic liver disease in China. Mr. Baharaff concluded, "It’s important that we are undertaking this expansion now and assuming a leadership position in this strategic market. This trial will contribute to the extension of the clinical development of Aramchol internationally and, in particular, in China, where CFDA regulations demands full clinical development before approval.”

About Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis:

Nonalcoholic fatty liver disease (NAFLD) is the most common cause of chronic liver disease in the United States and it affects almost 30% of adults in Western countries. With climbing obesity rates and more sedentary patient populations, the prevalence of NAFLD is increasing worldwide and is becoming the predominant cause of chronic liver disease in parts of the world. NAFLD represents a spectrum of diseases ranging from simple excess liver fat, or steatosis, to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality in persons who drink little or no alcohol. NASH represents the more severe end of this spectrum and is characterized by steatosis, ballooning degeneration and lobular inflammation with or without fibrosis. Long-term risks of NASH include cardiovascular disease, cirrhosis, hepatocellular carcinoma and end stage liver disease requiring liver transplantation.

About Galmed Pharmaceuticals Ltd.:

Galmed is a clinical-stage biopharmaceutical company focused on the development of a novel, once-daily, oral therapy for the treatment of liver diseases utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, Aramchol™, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need. Galmed is currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol™ in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

Forward-Looking Statements:

This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Applicable risks and uncertainties include risks and uncertainties associated with the timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on

Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016, and in other filings that Galmed has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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