Galmed Pharmaceuticals Ltd.
Form 6-K
September 22, 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 September 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): ¨

On September 22, 2016, Galmed Pharmaceuticals Ltd. (the “Company”) issued a press release announcing it has entered into an investigator initiated clinical trial agreement (the "Agreement") with the Regents of the University of California on behalf of its San Diego campus ("UCSD") to conduct a Phase I/IIA study (the "ARTISAN Study") entitled: "A Phase I-IIa Study to Assess Safety, Tolerability, Efficacy, and Pharmacokinetics of Aramchol in a NAFLD Juvenile Population” (the "Protocol"). The ARTISAN Study (ARamchol™ Trial to Improve Steatosis in Adolescent NAFLD) will be led by Jeffrey Schwimmer, MD, professor of pediatrics, UC San Diego School of Medicine and Director, Fatty Liver Clinic, Rady Children’s Hospital, San Diego. The performance of the study is subject to submission of the Protocol to the U.S. FDA and receipt of FDA IND approval. There is no certainty that the FDA IND approval will be obtained. The Study is currently expected to be initiated in the first half of 2017.

Pursuant to the terms of the Agreement, the Company shall provide its proprietary drug product candidate Aramchol™, without cost, to conduct the Study as required pursuant to the Protocol and shall provide funds to conduct the Study over the duration of the Study.

Under the Agreement, UCSD grants the Company a non-exclusive, royalty-free license to use any UCSD or Joint Invention (as defined in the Agreement) and Study data for its internal research and development purposes. Further, UCSD grants the Company a time-limited first right to negotiate a commercial, royalty-bearing, exclusive license, to make, use, and sell any patentable UCSD or Joint Invention conceived and reduced to practice in the performance of the research, for the term of any patent thereon.

All rights, title and interest in Study data shall be the sole and exclusive property of UCSD; however, the Company shall be entitled to make use of such Study data for legal purpose consistent with the informed consent, including publication and regulatory filings, after the earlier of the publication of the Study data by UCSD or upon the expiration of a period of eighteen (18) months from the completion of the Study. The Protocol and research design of the Study are the property of UCSD.

Either party may terminate the Agreement (i) upon thirty (30) days prior written notice to the other Party, in its sole discretion; (ii) upon written notice to the other Party, if the terminating Party determines that termination of the Study is necessary for the safety of the Study subjects; or (iii) upon the other party’s material breach if such party fails to cure such breach within thirty days after receiving written notice thereof. Upon receipt of notice of early termination, UCSD will stop screening subjects for and enrolling subjects in the Study and will discuss in good faith a plan to continue monitoring Study subjects as appropriate and determine an orderly winding down of the Study. Upon termination or expiration of the agreement, all CRFs outstanding must be completed and copies returned to the Company together with completed Study Drug inventory and records, and all Company Confidential Information (as defined in the Agreement). If the Agreement is terminated before completion of the Study, the Parties shall negotiate in good faith on the phase-out for Study subjects and subsequent treatment of Study subjects.

The Agreement includes customary indemnification provisions.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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).

Exhibit Index

Exhibit No.	**Description**
99.1	Press Release, dated September 22, 2016

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: September 22, 2016 By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer