
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 October 2016

001-36203
(Commission File Number)

CAN-FITE BIOPHARMA LTD.

(Exact name of Registrant as specified in its charter)

10 Bareket Street
KiryatMatalon, P.O. Box 7537
Petach-Tikva 4951778, 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 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): ____

This Report on Form 6-K (including exhibits thereto) is hereby incorporated by reference into the registrant's Registration Statements on Form F-3 (File Nos. 333-195124, 333-199033, 333-204795 and 333-209037), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

On October 13, 2016, Can-Fite BioPharma Ltd. issued a press release announcing that it has submitted the clinical trial protocol for its Phase II study of CF102 in the treatment of non-alcoholic fatty liver disease, the precursor to non-alcoholic steatohepatitis, to a leading Institutional Review Board in Israel. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated October 13, 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.

Can-FiteBioPharma Ltd.

Date: October 13, 2016

By: /s/ Pnina Fishman
Pnina Fishman
Chief Executive Officer

Can-Fite Submits Protocol for Phase II Trial of CF102 in the Treatment of NAFLD/NASH

- *Leading Israeli medical institutions Hadassah and Rabin Medical Centers to be included in the trial*
- *Study to enroll 60 patients with primary endpoint of reducing liver fat*
- *\$35 billion estimated treatment market by 2025*

PETACH TIKVA, Israel, October 13, 2016 -- Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory and liver diseases, cancer, and sexual dysfunction, today announced it has submitted the clinical trial protocol for its Phase II study of CF102 in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH), to a leading Institutional Review Board (IRB) in Israel. Top medical centers in Israel, including Hadassah Medical Center and Rabin Medical Center are expected to participate in the planned study by enrolling and treating patients.

“We are eager to commence our Phase II study in NAFLD/NASH, an indication for which there is no U.S. FDA approved drug. We view the submission of our clinical trial protocol as a major step forward,” stated Can-Fite CEO Dr. Pnina Fishman.

Based on the protocol that was submitted, Can-Fite's Phase II study, designed by world renowned Key Opinion Leaders in the field of liver diseases, will be a multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of CF102 in the treatment of NAFLD/NASH. The study will enroll approximately 60 patients with NAFLD, with or without NASH, and will have three arms, including two different dosages of CF102 and a placebo, given via oral tablets twice daily. The study's primary endpoints will be percent change from baseline in liver triglyceride (fat) concentration measured by nuclear magnetic resonance spectroscopy (NMRS) and safety. Secondary endpoints to be evaluated are the effects of CF102 on metabolic abnormalities in subjects with NAFLD, including body weight, waist circumference, serum triglyceride and high-density lipoprotein cholesterol levels, and serum liver transaminase. In addition, an assessment of the pharmacokinetics (PK) of CF102 and the A3 adenosine receptor (A3AR) biomarker will be evaluated prior to treatment and its correlation to patients' response to the drug will be analyzed upon study conclusion. Furthermore, the exploratory objective of this study is to evaluate the effects of CF102 on relevant biomarkers, such as adiponectin, leptin, C-reactive protein (CRP), and liver stiffness as determined by Fibroscan. The trial design is based on preclinical studies showing CF102's efficacy in reducing liver fat in NASH models as compared to placebo, improving liver function, and regenerating liver cells.

Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach \$35-40 billion in size by 2025.

About NAFLD/NASH

NAFLD is characterized by excess fat accumulation in the form of triglycerides (steatosis) in the liver. According to a recent study published in *Hepatology*, an estimated 25% of the population in the U.S. has NAFLD, with a higher prevalence in people with type II diabetes. Incidence is increasing based on rising obesity rates. NAFLD includes a range of liver diseases, with NASH being the more advanced form, manifesting as hepatic injury and inflammation. According to the NIH, the incidence of NASH in the U.S. is believed to affect 2-5% of the population. The spectrum of NAFLDs resembles alcoholic liver disease; however, they occur in people who drink little or no alcohol. If untreated, NASH can lead to cirrhosis and liver cancer.

About CF102

CF102 is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug. In Can-Fite's pre-clinical and clinical studies, CF102 has demonstrated a robust anti-tumor effect via deregulation of the Wnt signaling pathway, resulting in apoptosis of liver cancer cells. Based on preclinical data showing CF102 has strong liver protective properties, Can-Fite intends to initiate a Phase II study in NASH. Can-Fite has received Orphan Drug Designation for CF102 in Europe and the U.S., as well as Fast Track Status in the U.S. as a second line treatment for hepatocellular carcinoma.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI) is an advanced clinical stage drug development Company with a platform technology that is designed to address multi-billion dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is scheduled to enter Phase III trials in 2016 for two indications, rheumatoid arthritis and psoriasis. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug CF102 is in Phase II trials for patients with liver cancer and is slated to enter Phase II for the treatment of non-alcoholic steatohepatitis (NASH). CF102 has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. CF602, the Company's third drug candidate, has shown efficacy in the treatment of erectile dysfunction in preclinical studies and is being prepared for an IND submission to the FDA and a Phase I trial. These drugs have an excellent safety profile with experience in over 1,000 patients in clinical studies to date. For more information please visit: www.can-fite.com.

Forward-Looking Statements

This press release may contain forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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