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 January 2016

001-36203
(Commission File Number)

CAN-FITE BIOPHARMA LTD.

(Exact name of Registrant as specified in its charter)

10 Bareket Street
Kiryat Matalon, 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333-199033 and 333-204795), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 January 5, 2016, Can-Fite BioPharma Ltd. issued a press release announcing that it has submitted its Phase III clinical study protocol to the Institutional Review Board (IRB) of Barzilai Medical Center in Israel and will file similar submissions in several European countries, Canada and the U.S. 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 January 5, 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-Fite BioPharma Ltd.

Date January 5, 2016

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

Exhibit 99.1

Can-Fite Submits Phase III Protocol to IRB for CF101 in the Treatment of Rheumatoid Arthritis

- ***Pivotal Phase III trial to enroll approximately 456 patients for robust statistically significant data***
- ***Phase III protocol submission follows Can-Fite's successful meeting with the Medical Products Agency (MPA) in Sweden***
- ***CF101 to serve rheumatoid arthritis market forecast to reach $38.5 B by 2017***

PETACH TIKVA, Israel, January 5, 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 diseases, cancer and sexual dysfunction, announced today an important milestone towards beginning the pivotal Phase III trial of its lead drug candidate CF101 in the treatment of rheumatoid arthritis. Can-Fite has submitted its Phase III clinical study protocol to the Institutional Review Board (IRB) of Barzilai Medical Center in Israel and will file similar submissions in several European countries, Canada and the U.S.

The Phase III protocol submission in Israel follows a successful meeting that Can-Fite concluded on December 8, 2015 with the Medical Products Agency (MPA) in Sweden regarding the European registration of CF101 in the treatment of rheumatoid arthritis. During the meeting, Can-Fite presented data from the Company's successful Phase II trial in rheumatoid arthritis and the CF101 rheumatoid arthritis clinical registration strategy was discussed. Agreement was reached on MPA's expectations for the registration plan and the Phase III patient population, dosing, study endpoints, treatment duration and placebo management.

The Company plans to conduct a Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study that will investigate the efficacy and safety of CF101 administered orally twice daily for 16 weeks to patients with active rheumatoid arthritis treated with conventional drugs. The study will have three arms, a 1 mg CF101 dose, a 2 mg CF101 dose and placebo, given orally twice daily in the form of tablets. Approximately 456 patients are expected to be enrolled in the study, where sample size has been estimated to demonstrate definitive efficacy of CF101 based on the ACR20 response. The A3 adenosine receptor biomarker will be evaluated prior to treatment and its correlation to patients' response to the drug will be analyzed upon study conclusion.

"We are now concluding the preparatory work to file our Phase III protocol with the European Medicines Agency (EMA) in the first quarter of 2016," stated Can-Fite CEO Dr. Pnina Fishman. "Our newly strengthened cash position following our recent fund raises totaling approximately $14 million is intended to support this pivotal trial."

Rheumatoid arthritis is a chronic, systematic, autoimmune inflammatory disease that manifests as joint pain, stiffness, and swelling. According to Visiongain, the global rheumatoid arthritis market is forecasted to reach $38.5 billion by 2017.

About CF101

CF101 is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with a favorable therapeutic index demonstrated in Phase II clinical studies. CF101 is currently under development for the treatment of autoimmune inflammatory diseases including rheumatoid arthritis (completed Phase II) and psoriasis (completed Phase II/III).

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 CF101 drug candidate is currently under advanced clinical development, preparing to enter Phase III trials for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug CF102 is in Phase II trials for patients with advanced liver cancer and is being investigated as a potential treatment for non-alcoholic steatohepatitis (NASH). CF102 has been granted Fast Track Designation as a second line treatment for hepatocellular carcinoma (HCC) by the U.S. FDA. It has also received Orphan Drug Designation for the treatment of HCC in the U.S. and Europe, as well as being approved for Compassionate Use by Israel's Ministry of Health. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. The Company's CF602 has shown efficacy in the treatment of erectile dysfunction. Can-Fite has initiated a full pre-clinical program for CF602 in preparation for filing an IND with the U.S. FDA in this indication. These drugs have an excellent safety profile with experience in over 1,200 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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