# 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

001-36203 (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333-204795 and 333-209037), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 June 6, 2016, a Special General Meeting of Shareholders of Can-fite BioPharma Ltd. (the "Company") and a Special General Meeting of Series 11 Warrant Holders of the Company approved, in accordance with the majority required, a proposal to (i) amend the terms of the Company's Series 11 Warrants by extending the expiration date of the Series 11 Warrants from April 30, 2016 to October 31, 2016 and allowing the Series 11 Warrants to be exercised on any trading day. Such proposals were described in the Company's Notice of Special General Meeting of Shareholders and Holders of Series 11 Warrants, dated April 25, 2016, and in its Proxy Statement, dated April 25, 2016, attached as Exhibit 99.1 to the Company's Form 6-K that was furnished to the U.S. Securities and Exchange Commission on April 25, 2016.

On June 7, 2016, the Company issued a press release announcing that it has submitted its protocol design to the European Medicines Agency (EMA) for a Phase III trial and Registration Plan for the Company's lead compound Piclidenoson (CF101) in the treatment of psoriasis. 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 June 7, 2016
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## 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: June 7, 2016

By: <u>/s/ Pnina Fishman</u>
Pnina Fishman

Pnina Fishman Chief Executive Officer

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#### Can-Fite Submits Psoriasis Phase III Protocol and Registration Plan to EMA for Piclidenoson (CF101)

- Phase III protocol is a head-to-head trial comparing Piclidenoson to Otezla®
- Former Phase II/III study showed Piclidenoson has better safety and efficacy at week 32 as compared to Otezla®
- Global psoriasis market estimated to reach \$9 billion by 2018

PETACH TIKVA, Israel, June 07, 2016 -- <u>Can-Fite BioPharma Ltd.</u> (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, today announced it has submitted its protocol design to the European Medicines Agency (EMA) for a Phase III trial and Registration Plan for the Company's lead compound Piclidenoson (CF101) in the treatment of psoriasis. This follows a pre-submission meeting the Company had with the EMA.

The planned Phase III trial is a randomized, double-blind, placebo- and active-controlled study that will investigate the efficacy and safety of daily Piclidenoson administered orally compared to apremilast (Otezla®) in approximately 370 patients with moderate-to-severe plaque psoriasis. The study is designed to have four arms, Piclidenoson 2 mg, 3 mg, matching apremilast 30 mg, or matching placebo in a 3:3:3:2 ratio. Medication will be taken orally twice daily for 32 weeks in a double-blinded fashion. The primary end point will be the proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response of  $\geq$ 75% (PASI 75) at week 32.

Data from Can-Fite's former Phase II/III study showed that at weeks 24 and 32, Piclidenoson's efficacy as measured by PASI compares well to Otezla®, the recently registered oral drug, marketed by Celgene. The global psoriasis market is estimated to reach \$9 billion by 2018 (Visiongain), and Otezla® sales are estimated to be \$2.35 billion by 2020 (DrugAnalyst).

"Submission of this Phase III protocol design to the EMA marks the next step in our plan to provide patients with a new safe oral treatment for psoriasis. We plan to conduct the Phase III study globally," stated Can-Fite CEO, Dr. Pnina Fishman.

### **About Piclidenoson (CF101)**

Piclidenoson 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. Piclidenoson 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 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 EMA. 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 other

#### Contact

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