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 2023

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 ☐

The first four paragraphs of the press release attached to this Form 6-K are hereby incorporated by reference into the registrant's Registration Statements on Form S-8 (File Nos. 333-227753 and 333-271384) and Form F-3 (File Nos. 333-195124, 333-236064, 333-249063 and 333-262055), to be a part there of from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

On June 29, 2023, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Receives U.S. FDA's Go Ahead for Piclidenoson Psoriasis Registration Plan". 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 29, 2023

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.

Date: June 29, 2023

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

Exhibit 99.1

Can-Fite Receives U.S. FDA's Go Ahead for Piclidenoson Psoriasis Registration Plan

- ***FDA encouraged the Company to enroll adolescent patients due to the strong safety profile of the drug demonstrated over the development history and prior clinical studies***

PETACH TIKVA, Israel, June 29, 2023 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncology, inflammatory, and liver diseases, today announced that it received feedback and advice from the U.S. Food and Drug Administration (FDA) with respect to non-clinical and clinical development and registration plans for Piclidenoson for the treatment of patients with moderate to severe plaque psoriasis.

The FDA had a positive view of the non-clinical studies conducted by the Company and the accumulated safety data that the Company submitted to the agency as part of the registration plan.

The FDA provided advice on the randomized, double-blind, placebo-controlled Phase 3 clinical trial protocol with Piclidenoson that is aimed at demonstrating clinical safety and efficacy for the treatment of patients with moderate to severe plaque psoriasis. The FDA requested two Phase 3 safety and efficacy studies and also encouraged the Company to enroll adolescent patients due to the strong safety profile of the drug demonstrated over the development history and prior clinical studies. To harmonize the requests of the European Medicines Agency (EMA) and the FDA, Can-Fite plans to conduct two Phase 3 studies in parallel, including adolescent patients.

Can-Fite believes the inclusion of adolescent patients in one or both of the Phase 3 studies significantly broadens the market launch potential of the drug. Psoriasis affects millions of people worldwide, including a significant number of adolescents who endure the physical and emotional burden of this challenging disease. There are limited treatment options available for adolescent patients in the U.S. Otezla is not approved for use in adolescents, and existing oral options include steroids and off-label use of retinoids (acitretin) and methotrexate, both of which carry significant safety and tolerability issues for teenagers. The Company believes that Piclidenoson represents a promising oral option for this underserved population.

Upon positive conclusion of the Phase 3 program, the Company plans to submit a New Drug Application (NDA) to the U.S. FDA and Marketing Authorization Plan (MAA) to the EMA.

"We are delighted to share the positive feedback that we received from the U.S. FDA and we believe that Piclidenoson's oral dosage and excellent safety record, combined with its progressive effectiveness over time, make it ideally suited for the chronic treatment of psoriasis," stated Can-Fite CEO Dr. Pnina Fishman.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF) 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, liver, and inflammatory disease. The Company's anti-inflammatory drug Piclidenoson reported topline results in a Phase 3 trial for psoriasis and is expected to commence a pivotal Phase 3 program. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase 2b trial for the treatment of non-alcoholic steatohepatitis (NASH), enrollment is expected to commence in a Phase 3 trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase 2a study in pancreatic cancer. Namodenoson has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for HCC by the U.S. Food and Drug Administration. Namodenoson 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. These drugs have an excellent safety profile with experience in over 1,500 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. All statements in this communication, other than those relating to historical facts, are "forward looking statements". 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the "Risk Factors" section of Can-Fite's Annual Report on Form 20-F filed with the SEC on March 30, 2023 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

Contact

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