
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 July 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 ☐

On July 17, 2023, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite: Granted Breakthrough Abstract Award for Namodenoson in Treatment of Advanced Liver Cancer by ASCO Conquer Cancer Foundation”. 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 July 17, 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: July 17, 2023

By: /s/ Motti Farbstein
Motti Farbstein
Chief Executive Officer

Can-Fite: Granted Breakthrough Abstract Award for Namodenoson in Treatment of Advanced Liver Cancer by ASCO Conquer Cancer Foundation

- *Can-Fite's novel approach for the treatment of advanced liver cancer will be presented at the American Society of Clinical Oncology (ASCO) Breakthrough Meeting in Japan on August 4th 2023*
- *Namodenoson is in pivotal Phase 3 study for the treatment of advanced hepatocellular carcinoma (HCC)*
- *A patient from the prior Phase 2b study is cancer-free >6 years following initial treatment with Namodenoson*

PETACH TIKVA, Israel, July 17, 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 its abstract titled "A novel approach for the treatment of advanced hepatocellular carcinoma (HCC)" is one of the highest scoring abstracts and has won the prestigious Breakthrough Abstract Award from Conquer Cancer®, the ASCO Foundation, and the 2023 ASCO Breakthrough Program Committee.

Can-Fite's Chief Scientific Officer, Founder, and Executive Chairman, Dr. Pnina Fishman, will present the poster at the ASCO Breakthrough Meeting which will take place August 3 – 5, 2023 in Yokohama, Japan.

Namodenoson has received significant acknowledgment in the scientific and medical community, as evidenced by the numerous peer-reviewed publications and conferences in which it has been published and presented. Currently being evaluated in a pivotal Phase 3 multinational registration trial for the treatment of HCC and underlying Child Pugh B7, Namodenoson has also completely cleared cancer in an HCC patient who was enrolled in Can-Fite's Phase 2b HCC trial. The patient continues to be treated through a compassionate use program in Romania, where she remains cancer-free more than six years following her first dose of Namodenoson.

"We are honored to receive this prestigious award from Conquer Cancer and ASCO," Dr. Fishman stated. "Our Phase 3 registration trial is designed to treat patients who have tried, yet not benefitted from the few other FDA-approved HCC treatments on the market today. We are hopeful that Namodenoson, with its liver-protective properties, can safely prolong life for advanced liver cancer patients."

About Namodenoson

Namodenoson was evaluated in Phase 2 trials for two indications, as a second line treatment for hepatocellular carcinoma (HCC), and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). It is currently in a Phase 2b trial for NASH and a pivotal Phase 3 for HCC. Namodenoson 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.

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. 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.

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