
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 ☐

On June 13, 2023, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite to Submit IND for the Treatment of Pancreatic Cancer Patients with Namodenoson”. 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 13, 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 13, 2023

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

Can-Fite to Submit IND for the Treatment of Pancreatic Cancer Patients with Namodenoson***Namodenoson's robust effect reached 90% inhibition of pancreatic cancer growth in pre-clinical studies***

PETACH TIKVA, Israel, June 13, 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 is doing all the preparatory work for an FDA Investigational New Drug (IND) submission for the treatment of pancreatic carcinoma with Namodenoson.

Pre-clinical studies demonstrate a robust dose dependent anti-proliferative effect of Namodenoson on pancreatic carcinoma cells originating from both male and female patients, reaching 90% growth inhibition.

An open-label Phase 2 exploratory trial to assess the safety and efficacy of Namodenoson in the treatment of patients with pancreatic cancer who have received at least one previous systemic therapy will be initiated. The study will enroll patients in Israel at the Rabin Medical Center and will be conducted by Dr. Salomon Stemmer, an oncology key opinion leader and Professor at the Institute of Oncology, Rabin Medical Center, Israel. Patients will receive Namodenoson at a dose of 25 mg orally, twice daily. Study endpoints will include safety, objective response, progression-free survival, duration of response, disease control (defined as an objective response or stable disease), and overall survival.

The IND submission will cross reference all the data previously shared with the FDA related to the development of Namodenoson for the treatment of advanced liver cancer. Can-Fite is currently enrolling patients in a pivotal Phase 3 study in hepatocellular carcinoma, in agreement with both the FDA and the European Medicines Agency (EMA).

"We are making progress towards Namodenoson's first clinical trial in pancreatic carcinoma. Once this study is underway, Can-Fite's pipeline will include two oncology indications with Namodenoson in clinical trials. We hope our oral anti-cancer drug, with its good safety and robust anticancer effect, will help and support patients with this devastating disease," stated Can-Fite CEO Dr. Pnina Fishman.

The highest incidence rates for pancreatic cancer are in Asia, Europe, and North America. According to the American Society of Clinical Oncology (ASCO), in 2020, an estimated 496,000 people were diagnosed with pancreatic cancer globally and an estimated 466,000 died from the disease. The 5-year survival rate for people with pancreatic cancer in the U.S. is 11%. Acumen Research estimates the global pancreatic cancer therapeutics market was valued at approximately \$3.6 billion in 2021 and is projected to grow to approximately \$6.6 billion by 2030.

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, a pivotal Phase 3 for HCC, and is headed into a Phase 2a for pancreatic cancer. 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), a Phase 3 trial for hepatocellular carcinoma (HCC) is enrolling patients, 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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