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 May 2024

001-36203
(Commission File Number)

CAN-FITE BIOPHARMA LTD.
(Exact name of Registrant as specified in its charter)

26 Ben Gurion Street
Ramat Gan 5257346 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 paragraph of the press release attached to this Form 6-K is hereby incorporated by reference into the registrant's Registration Statements on Form S-8 (File Nos. 333-227753, 333-271384 and 333-278525) and Form F-3 (File Nos. 333-195124, 333-236064, 333-249063, 333-262055 and 333-276000), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 9, 2024, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite: FDA grants IND Clearance for Namodenoson to Treat MASH Patients in a Phase IIb Study”. 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 May 9, 2024

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: May 9, 2024

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

Exhibit 99.1

Can-Fite: FDA grants IND Clearance for Namodenoson to Treat MASH Patients in a Phase IIb Study

RAMAT GAN, Israel, May 09, 2024 – Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announces that the U.S. Food and Drug Administration (FDA) has granted Investigational New Drug (IND) clearance for Namodenoson, for the treatment of patients with metabolic dysfunction-associated steatohepatitis (MASH), also known as non-alcoholic steatohepatitis (NASH), for the Company's ongoing Phase IIb clinical study.

Namodenoson is a small molecule orally bioavailable drug, targeting the A3 adenosine receptor, over-expressed on the surface of liver pathological cells in MASH but not normal cells. This potentially makes Namodenoson an ideal specific candidate for the treatment of MASH. Indeed, in a Phase IIa clinical study Namodenoson, has been shown to reduce hepatic steatosis, inflammation and fibrosis, with an excellent safety profile. Currently Can-Fite is enrolling patients for a Phase IIb clinical study in Europe and in Israel and the IND approval by FDA will allow for the recruitment of patients in the US.

The Phase IIb trial is a multicenter, randomized, double-blind, placebo-controlled study in subjects with biopsy-confirmed MASH. The primary efficacy objective of the trial is to evaluate the efficacy of Namodenoson as compared to placebo in 140 subjects with MASH, as determined by a histological endpoint. Eligible subjects are randomly assigned in a 2:1 ratio to oral doses of Namodenoson 25 mg every 12 hours or a matching placebo for 36 weeks.

"The IND activation for the treatment of MASH patients with Namodenoson, opens the gate for the enrolment of US based patients and will contribute to the heterogeneity of the population of this study," said Motti Farbstein, Can-Fite CEO. " As we are already enrolling patients for this study, we hope that in the next few months, we will complete recruitment. We are committed to improve the lives of MASH patients and based on the efficacy of the drug in the Phase IIa study, we are proud to develop a new potential treatment to address this disease."

Rates of MASH are increasing in the United States in concert with increasing rates of obesity and diabetes and is estimated to affect 2-5% of adult Americans. By 2028, Vantage Market Research estimates the addressable pharmaceutical market for MASH will reach $21.9 billion in size. In March 2024, Madrigal Pharmaceuticals announced FDA approval of Rezdiffra (resmetirom) for the treatment of MASH with moderate to advanced liver fibrosis, potentially paving the way for more drugs that target this huge market.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). 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 lead drug candidate, Piclidenoson recently reported topline results in a Phase III trial for psoriasis and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of steatotic liver disease (SLD), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa 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 1,600 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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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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