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 March 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 March 13, 2023, Can-Fite BioPharma Ltd. (the "Company") issued a press release entitled "Can-Fite to Treat Decompensated Liver Cirrhosis Patients with Namodenoson Under Compassionate Use Setting". 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 March 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: March 13, 2023

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

Exhibit 99.1

Can-Fite to Treat Decompensated Liver Cirrhosis Patients with Namodenoson Under Compassionate Use Setting

- ***Liver organ shortage puts patients at risk of death from decompensated cirrhosis with no treatment options available***
- ***Liver cirrhosis treatment market is estimated to reach approximately $15 billion in the U.S. by 2030***

PETACH TIKVA, Israel, March 13, 2019 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, announced today that patients with decompensated cirrhosis, an advanced form of cirrhosis associated with liver failure for which there are no therapeutic options other than liver transplantation, will be treated with Namodenoson at the Soroka Medical Center in Israel under compassionate use. This drug is currently used in a pivotal Phase III study for patients with advanced liver cancer and a Phase IIb study for NASH.

Decompensated cirrhosis is defined as an acute deterioration in liver function in a patient with cirrhosis and is characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome, or variceal hemorrhage. While some drugs can treat symptoms, there is no therapeutic approach that has shown efficacy in slowing disease progression.

An estimated 10.6 million people globally had decompensated cirrhosis in 2017, with few treatment options available aside from liver transplants if the decompensated cirrhosis has reached an advanced stage. Underscoring the need for an effective treatment, the American Liver Foundation states there are more people who need a liver than supply available, and some people can be on the wait list for a liver transplant for more than 5 years. The treatment of liver cirrhosis in the U.S. is estimated to become an approximately $15 billion market by 2030.

Ohad Etzion, MD, Head, Hepatology Department at the Soroka Medical Center, Beer Sheva, Israel, the Investigator and Initiator of this study commented, “Given the evidence of Namodenoson’s clinical benefit in patients with decompensated cirrhosis for whom there is no accepted well established treatment, Namodenoson may give hope to this patient population in the compassionate use setting.”

Compassionate use allows doctors and their patients the option of early access to investigational new drugs, under closely controlled and monitored circumstances, when a patient who is facing serious illness has exhausted all available treatment options.

Namodenoson’s unique characteristics of inducing hepato-protective effects make it suitable to treat patients with decompensated cirrhosis. In a Phase II study, Namodenoson was found to increase overall survival in advanced liver cancer patients defined as Child Pugh B7, known to suffer from cirrhosis. In a Phase IIa NASH study, Namodenoson met its primary efficacy endpoint showing positive activity manifested in anti-inflammatory, anti-steatotic, and antifibrotic effects with a very favorable safety profile.

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. Can-Fite’s liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH), and enrollment is expected to commence in a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver 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 24, 2022 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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