

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 2021

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

On July 8, 2021, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Gears Up to Initiate Pivotal Phase III Liver Cancer Study". A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated July 8, 2021

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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 8, 2021

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

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Can-Fite Gears Up to Initiate Pivotal Phase III Liver Cancer Study

FDA Granted Namodenoson Orphan Drug and Fast Track Status

PETACH TIKVA, Israel, July 8, 2021 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced it has completed preparatory work ahead of the anticipated initiation of patient enrollment for its pivotal Phase III registration trial of Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

Can-Fite has received agreement from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) on the protocol and plans to submit it for Institutional Review Board (IRB) approvals in the coming weeks. Namodenoson has Orphan Drug status with both the FDA and EMA, as well as Fast Track Status with the FDA for the treatment of HCC. A compassionate use program has been ongoing in Israel.

The double blind, placebo-controlled trial will enroll 450 patients diagnosed with HCC and underlying Child Pugh B7 (CPB7) through clinical sites worldwide. Patients will be randomized to oral treatment with either 25 mg Namodenoson or matching placebo given twice daily. The primary efficacy endpoint of the trial is overall survival. Other oncology trial efficacy outcomes such as tumor radiographic response rates and median progression-free survival, as well as standard safety parameters, will be assessed.

The Company plans to conduct an interim analysis by an Independent Data Monitoring Committee (IDMC) after 50% of enrolled patients are treated. Namodenoson will be evaluated as a 2nd or 3rd line treatment for CPB7 patients in whom other approved therapies have not been or are no longer effective.

“We are eager to commence this study, as there is a dire need for a safe and effective treatment for patients with advanced liver disease, defined as CPB7, where Namodenoson has an advantage with its liver protective effect,” stated Can-Fite CEO Dr. Pnina Fishman.

According to the American Cancer Society, liver cancer accounts for more than 700,000 deaths globally each year. HCC is commonly aggressive with poor survival rates. As new drugs that effectively and safely treat HCC are developed and approved, the market for HCC treatments is estimated by Delveinsight to reach \$3.8 billion by 2027 for the G8 countries.

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: CFBI) 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, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH). 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, market risks and uncertainties, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. 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. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. 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 risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: 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 impact of the COVID-19 pandemic; 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; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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