

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 December 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): ____

The two first paragraphs of the press release attached to this Form 6-K are hereby incorporated by reference into the registrant's Registration Statements on Form S-8 (File No. 333-227753) and Form F-3 (File Nos. 333-195124, 333-236064, 333-237443 and 333-249063), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 December 20, 2021, Can-Fite BioPharma Ltd. issued a press release entitled "Liver Cancer Patient Treated with Can-Fite's Namodenoson Clears All Cancer Lesions Under Open Label Extension of Phase II 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 December 20, 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: December 20, 2021

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

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Liver Cancer Patient Treated with Can-Fite's Namodenoson Clears All Cancer Lesions Under Open Label Extension of Phase II Study

Pivotal Phase 3 Study to Commence Q1 2022

PETACH TIKVA, Israel, December 20, 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 that the last patient treated under an Open Label Extension program of its concluded Phase II study of Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer, experienced a Complete Response (CR) to Can-Fite's drug, meaning that all cancer lesions have cleared.

Under treatment with Namodenoson, the patient has now survived five years, during which time the clinical benefits of treatment have included the disappearance of ascites, normal liver function, and the disappearance of peritoneal carcinomatosis leading to complete clearance of all cancer lesions.

"Complete Response of HCC in an advanced stage is a rare but highly beneficial result in the field of liver cancer treatment. We are pleased that Namodenoson has contributed to the restored health and quality of life for this patient and family. It is our hope that our upcoming pivotal Phase III study will demonstrate Namodenoson's efficacy in treating patients with similarly advanced HCC and thereby potentially offer longer survival to liver cancer patients across the world," stated Can-Fite's Medical Director Dr. Michael Silverman.

In the first quarter of 2022, Can-Fite expects to commence patient enrollment in its pivotal Phase III trial for Namodenoson in the treatment of patients with advanced HCC with underlying Child Pugh B7 (CPB7) cirrhosis to support a New Drug Application (NDA) submission and approval. Both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have agreed with the design of the 471-patient study. Namodenoson has Orphan Drug Designation for HCC in the U.S. and Europe, has Fast Track Status in the U.S., and is currently treating liver cancer patients through a compassionate use program in Israel.

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, and inflammatory disease. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis. 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.

Contact

Can-Fite BioPharma

Motti Farbstein

info@canfite.com

+972-3-9241114
