
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 2020

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 first and second 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, 333-209037 and 333-220644), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 21, 2020, Can-Fite BioPharma Ltd. (the “Company”) issued a press release announcing that the U.S. Patent and Trademark Office (PTO) has issued a Notice of Allowance for the Company’s patent titled, “Method for treating NASH accompanied by fibrosis using CI-IB-MECA”. 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 21, 2020 |

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 21, 2020

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

Can-Fite Receives Notice of Allowance for Namodenoson Patent in the Treatment of NASH & NAFLD from U.S. Patent and Trademark Office

Patent allowance follows compelling Phase II data showing Namodenoson resolved all cases of NASH after 12 weeks of treatment, and it reduced hepatic fibrosis and steatosis in NAFLD and NASH patients

PETACH TIKVA, Israel, May 21, 2020 -- 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 the U.S. Patent and Trademark Office (PTO) has issued a Notice of Allowance for the Company's patent titled, "Method for treating NASH accompanied by fibrosis using CI-IB-MECA". The allowance follows Can-Fite's recent announcement of highly encouraging data from its Phase II study of its drug candidate Namodenoson, generically known as CI-IB-MECA, in the treatment of non-alcoholic fatty liver disease (NAFLD) with or without non-alcoholic steatohepatitis (NASH).

The allowed patent covers the use of the A3 adenosine receptor (A3AR) in reducing ectopic fat accumulation, particularly in fatty liver. The patent specifically addresses preparation of a pharmaceutical composition for reducing fat accumulation and a method of treating conditions associated with fat accumulation such as fatty liver diseases including NASH and NAFLD.

Can-Fite recently announced findings from its Phase II study of Namodenoson in the treatment of patients with NAFLD with or without NASH. The study achieved its efficacy endpoints in a dose dependent and statistically significant manner, while continuing to demonstrate a good safety profile. The Phase II data revealed that the 25 mg dose of Namodenoson resolved significantly all cases of NASH, representing 25% of the 25 mg treated group, as compared to an increase in new NASH cases in the placebo group from a baseline of 0 to 5.9%. Namodenoson dosed at 25 mg reduced hepatic fibrosis (scar tissue in the liver resulting from the liver trying to repair itself), reduced steatosis (fat buildup in the liver), and improved the FAST score, a measure for NASH (liver stiffness and an enzymatic biomarker of liver damage).

"We are very pleased to receive this Notice of Allowance from the U.S. PTO at this time, immediately following an analysis of Phase II data that show Namodenoson is highly effective in treating and reversing fatty liver. At the optimal 25 mg dosage, Namodenoson eliminated NASH in the Phase II patient population. The protection provided by the allowed patent has a high value for us, as we move forward into advanced stage clinical trials in this indication, and as we evaluate distribution partnerships for Namodenoson," stated Can-Fite CEO, Dr. Pnina Fishman.

An estimated 85 million Americans have NAFLD, which may lead to an exponential rise in incidence of NASH, a more severe form of NAFLD, to close to 43 million Americans in the next five years. The NASH treatment market is estimated to reach \$35-40 billion by 2025.

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, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Piclidenoson has been approved for a pilot clinical trial in Israel to treat COVID-19 infected patients with moderate-to-severe symptoms. 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 successfully achieved its primary endpoint in a Phase II 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 recent outbreak of coronavirus; 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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