
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 February 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 February 14, 2023, Can-Fite BioPharma Ltd. issued a press release entitled “Novel Approach to Treating Advanced Liver Cancer with Namodenoson Published in Leading Scientific Journal: 12-Month Survival of 44% for Namodenoson vs. 18% for Placebo”. 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 February 14, 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: February 14, 2023

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

Novel Approach to Treating Advanced Liver Cancer with Namodenoson Published in Leading Scientific Journal: 12-Month Survival of 44% for Namodenoson vs. 18% for Placebo

- *Namodenoson is being evaluated in a pivotal Phase III study*
- *Namodenoson is approved for compassionate use in the treatment of liver cancer in Israel and Romania*

PETACH TIKVA, Israel, February 14, 2023 -- 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 *Purinergic Signalling*, a peer-reviewed scientific journal focused on molecules which target adenosine receptors, published an article titled “Targeting the A3 adenosine receptor to treat hepatocellular carcinoma: anti-cancer and hepatoprotective effects” authored by Can-Fite’s CEO Dr. Pnina Fishman and others.

The article includes a review of the novel approach for treating advanced liver cancer with Namodenoson, a small molecule orally bioavailable drug which specifically kills cancer cells and leaves normal liver cells unharmed. Efficacy and safety data are presented from Phase I and II human clinical studies. Treatment with Namodenoson resulted in longer overall survival in patients with advanced liver cancer as defined by Child Pugh B (CPB) stage in a statistically significant manner. The drug has shown to have a very favorable safety profile and exert a protective effect on liver cancer cells.

Currently, Namodenoson is being evaluated in a pivotal Phase III study. The study protocol has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) with 450 patients to be enrolled in Israel, Europe, and the U.S. An interim data analysis will be performed.

Namodenoson has been granted both Orphan Drug and Fast Track designations by the FDA and has received Orphan Drug status with the EMA.

“With Namodenoson, we are aiming to treat patients with the greatest need—those with advanced liver cancer CPB. Moreover, this category of patients are typically not enrolled by other clinical studies due to the severity of their disease,” Dr. Fishman stated. “We are hopeful that Namodenoson’s novel approach may be effective in our current pivotal Phase III trial based on positive results in our prior Phase II study with this advanced liver cancer population. Additionally, we are highly encouraged by the case of a patient from the Phase II study who cleared all liver cancer and remains cancer-free for six years while treated with Namodenoson.”

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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