
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 2022

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 December 28, 2022, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite Updates: Namodenoson Increases Survival for the Most Severe Patients”. 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 December 28, 2022

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 28, 2022

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

Can-Fite Updates: Namodenoson Increases Survival for the Most Severe Patients with Advanced Liver Cancer

- *Results to be shared at Biotech Showcase during JP Morgan conference week in San Francisco and at BIO-CEO in New York*
- *An advanced CPB liver cancer patient remains clear of cancer 6 years following treatment with Namodenoson*
- *While CPB patients are typically excluded from liver cancer clinical studies due to low expected response rates, Namodenoson-treated CPB7 patients had statistically significant overall survival gain*

PETACH TIKVA, Israel, December 28, 2022 -- 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 provided an update on its clinical program for Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. A pivotal Phase III registration study is open for enrollment of the most advanced liver cancer patients. At two upcoming bio-partnering conferences, Can-Fite will be presenting the latest data comparing the response of liver cancer patients to those with HCC Child-Pugh B (CPB), the most advanced liver cancer. The Company will also share the latest findings on a CPB liver cancer patient who remains cancer-free 6 years after she began treatment with Namodenoson.

Can-Fite's prior Phase II study showed that median overall survival in the CPB7 patient population was 6.8 months for those treated with Namodenoson as compared to 4.3 months for those treated with placebo. The < 1-year survival in the whole patient population was 32% in the namodenoson treated group vs. 14% (p= 0.058) in the placebo treated patients whereas in the CPB7 population 44% survival was found in the namodenoson treated group vs. 18% in the placebo treated one (p=0.028). An article published in the peer-reviewed journal *Cancers* regarding Can-Fite's Phase II study reported on the fact that CPB patients are generally excluded from clinical studies due to their poor prognosis and low expected response rate and that as of July 2020, clinicaltrials.gov listed 110 enrolling/active Phase II or III clinical studies in advanced HCC, all of which excluded CBP patients, except for only two studies in addition to Can-Fite's.

"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 "Our Phase III pivotal Namodenoson study is open for enrollment of CPB7 patients who have tried but not benefitted from other treatments on the market. We are optimistic that Namodenoson can help these patients based on the overall survival benefit already demonstrated in our Phase II study. At the upcoming bio-partnering conferences, we will be sharing extensive data that compares how the overall liver cancer population is treated, while the CPB patient population has few options and there are very few drug developers that will even allow them into their studies."

Can-Fite has received agreement from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) on its Phase III pivotal liver cancer study which is now open for enrollment. 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. The double blind, placebo-controlled trial will enroll 450 patients diagnosed with HCC and underlying 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.

An interim analysis will be conducted 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.

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.

Conference Schedule:

Biotech Showcase: The Investor Conference for Innovators – San Francisco, Sari Fishman Ph.D. will participate.

Meeting Dates: January 9-11, 2023

Location: Hilton San Francisco Union Square

For more information to request a meeting please register here

BIO CEO & Investor Conference – New York, Motti Farbstein CFO will participate.

Meeting Dates: February 6-7, 2023

Location: New York Marriott Marquis

For more information to request a meeting please register here

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 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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