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 September 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 September 27, 2023, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Novel Approach for the Treatment of Pancreatic Carcinoma with Namodenoson Receives Appreciation of the American Association of Cancer Research (AACR)". 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 September 27, 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: September 27, 2023

By: /s/ Motti Farbstein
Motti Farbstein
Chief Executive Officer and Chief Financial Officer

Can-Fite Novel Approach for the Treatment of Pancreatic Carcinoma with Namodenoson Receives Appreciation of the American Association of Cancer Research (AACR)

- ***Namodenoson robustly inhibits pancreatic carcinoma growth in pre-clinical studies, via inhibition of KRAS and Wnt pathways***
- ***Poster summarizing the inhibitory effect of Namodenoson in pancreatic carcinoma is presented today at the AACR conference***
- ***Exploratory Phase II pancreatic cancer study protocol has been developed and is to be submitted to ethical committees in Israel and the U.S.***

PETACH TIKVA, Israel, September 27, 2023 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncology, inflammatory and liver diseases, today announced that its study titled "Namodenoson Inhibits the Growth of Pancreatic Carcinoma via De-regulation of the Wnt/β-catenin Signaling Pathway" has been accepted for a poster presentation at the AACR Special Conference on Pancreatic Cancer, held from September 27-30, 2023, in Boston, Massachusetts.

The pre-clinical studies presented in the poster used advanced pancreatic carcinoma patient cells that were treated with Namodenoson both in tissue cultures and in *in vivo* studies. Namodenoson treatment resulted in a significant growth inhibition and de-regulation of two signal transduction pathways, the Wnt and the KRAS, both of which are responsible for the etiology and pathology of this devastating disease.

Can-Fite completed the development of an exploratory Phase II protocol in patients with pancreatic carcinoma who have failed first line treatment and plans to shortly submit it for approval to medical sites in Israel and the U.S. Safety and efficacy endpoints including objective response, progression-free survival, duration of response, disease control, and overall survival will be monitored.

"The robust inhibition of pancreatic carcinoma growth both *in vitro* and *in vivo*, together with the definitive mechanism of action is a strong basis for evaluating Namodenoson in patients with pancreatic carcinoma where chemotherapeutic drugs have a very limited effect. We are very happy that the AACR granted us the opportunity to present these encouraging data and to discuss the very important results with the leading global experts in this field," stated Prof. Pnina Fishman, CSO & Executive Chairman of Can-Fite.

About Pancreatic Cancer

The highest incidence rates for pancreatic cancer are in Asia, Europe, and North America. According to the American Society of Clinical Oncology (ASCO), in 2020, an estimated 496,000 people were diagnosed with pancreatic cancer globally and an estimated 466,000 died from the disease. The 5-year survival rate for people with pancreatic cancer in the U.S. is 11%. Acumen Research estimates the global pancreatic cancer therapeutics market was valued at approximately $3.6 billion in 2021 and is projected to grow to approximately $6.6 billion by 2030.

About Namodenoson

Namodenoson was evaluated in Phase 2 trials for two indications, as a second line treatment for hepatocellular carcinoma (HCC), and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). It is currently in a Phase 2b trial for steatotic liver disease and a pivotal Phase 3 for HCC. Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). 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 and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of steatotic liver disease (SLD), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic 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 1,600 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 30, 2023 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.

Contact

Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114