**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 July 2024

001-36203
(Commission File Number)

**CAN-FITE BIOPHARMA LTD.**
(Exact name of Registrant as specified in its charter)

**26 Ben Gurion Street**
**Ramat Gan 5257346 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 ☐

This Report on Form 6-K and the first paragraph of the press release attached hereto as Exhibit 99.1 are hereby incorporated by reference into the registrant's Registration Statements on Form S-8 (File Nos. 333-227753, 333-271384 and 333-278525) and Form F-3 (File Nos. 333-195124, 333-236064, 333-249063, 333-262055 and 333-276000), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 July 11, 2024, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Applies for FDA Orphan Drug Designation for Namodenoson in the Treatment of Pancreatic Cancer." A copy of this press release is furnished herewith as Exhibit 99.1.

**Exhibit Index**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated July 11, 2024 |



**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: July 11, 2024

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

**Can-Fite Applies for FDA Orphan Drug Designation for Namodenoson in the Treatment of Pancreatic Cancer**

PETACH TIKVA, Israel, July 11, 2024 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) for Orphan Drug Designation for its drug candidate Namodenoson in the treatment of pancreatic carcinoma.

An orphan drug is defined in the 1984 amendments of the U.S. Orphan Drug Act (ODA) as a drug intended to treat a condition affecting fewer than 200,000 persons in the United States. Orphan designation qualifies the sponsor of the product for seven-year marketing exclusivity to the first sponsor obtaining FDA approval of a designated drug, a tax credit equal to 50% of clinical investigation expenses, exemption/waiver of the Prescription Drug User Fee Act (PDUFA) application filing fees, assistance in the drug development process, and Orphan Products Grant funding eligibility.[1]

Can-Fite plans to start shortly a Phase IIa clinical study that will be a multicenter open-label trial in patients with advanced pancreatic adenocarcinoma whose disease has progressed on at least first line therapy. The trial will evaluate the safety, clinical activity, and pharmacokinetics (PK) of Namodenoson in this population. All patients will receive oral Namodenoson 25 mg administered twice daily for consecutive 28-day cycles. Patients will be evaluated regularly for safety. Approximately 20 evaluable patients will be enrolled. The primary objective of this trial is to characterize the safety profile of Namodenoson and the secondary objective is to evaluate the clinical activity as determined by the Objective Response Rate (ORR) using Response Evaluation Criteria in Solid Tumors (RECIST 1.1), Progression-Free Survival (PFS), Disease Control Rate (DCR), Duration of Response (DoR), and Overall Survival (OS). Can-Fite has already been granted Orphan Drug Status for Namodenoson for the indication of advanced liver cancer by the FDA and also by the EMA.

“The Orphan Drug application for Namodenoson underscores the high unmet medical need for a safe and efficacious drug for this devastating disease,” said Motti Farbstein, CEO of the Company. “This application further validates our belief that Namodenoson may potentially offer efficacy on top of the drug safety that has been already proved in other clinical indications. Upon marketing approval, receiving market exclusivity for Namodenoson would be significantly beneficial to Can-Fite.”

**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 NASH a Phase III 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.canfite.com.

1 https://www.fda.gov/media/83372/download

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**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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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**

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