
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 2025

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 ☐

On May 5, 2025, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite Has Raised \$175 Million in Total to Date for the Development of Namodenoson and Piclidenoson, Advancing into Pivotal Phase 3 Trials in Liver Cancer and Psoriasis”. A copy of this press release is furnished herewith as Exhibit 99.1.

1

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated May 5, 2025

2

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 5, 2025

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

3

Can-Fite Has Raised \$175 Million in Total to Date for the Development of Namodenoson and Piclidenoson, Advancing into Pivotal Phase 3 Trials in Liver Cancer and Psoriasis

Ramat Gan, Israel, May 05, 2025 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small-molecule drugs for oncological and inflammatory diseases, today announced that, it has raised \$175 million in funding to date. These funds have enabled the advancement of its lead drug candidates, Namodenoson and Piclidenoson, into pivotal Phase III studies for liver cancer and psoriasis, respectively.

Can-Fite is a recognized leader in the development of small-molecule therapeutics targeting the A3 adenosine receptor (A3AR), which is highly expressed in both inflammatory and cancer cells. Namodenoson, an orally bioavailable A3AR agonist, is currently enrolling patients in a pivotal Phase III study for advanced liver cancer. It has demonstrated selective targeting of liver and pancreatic tumor cells while sparing healthy tissue. Piclidenoson, also an orally administered A3AR agonist, is in a pivotal Phase III trial for patients with moderate-to-severe psoriasis.

Both candidates have shown favorable safety profiles, anti-cancer and anti-inflammatory properties, and promising efficacy in previous Phase II trials. Cumulative funding has also supported drug manufacturing, regulatory activities with the FDA and EMA, and the development of a broad patent portfolio providing extensive intellectual property protection.

In addition to its lead programs, Can-Fite is conducting a Phase IIa study of Namodenoson in pancreatic cancer, following successful preclinical studies demonstrating its ability to inhibit tumor growth by modulating the Wnt/ β -catenin, NF- κ B, and RAS signaling pathways. A Phase IIb trial in metabolic dysfunction-associated steatohepatitis (MASH) is also underway under an open IND with the FDA, leveraging Namodenoson's hepatoprotective effects.

To date, Can-Fite has signed seven commercialization agreements with strategic partners for the future marketing of its drug candidates upon regulatory approval. Can-Fite continues to engage with potential partners and seeks to sign additional commercialization agreements in the future.

Motti Farbstein, CEO of Can-Fite, commented: "This funding milestone reflects the strong confidence our investors and partners have in Can-Fite's scientific platform and clinical strategy. Progressing into pivotal Phase III trials marks a significant step toward bringing innovative, oral therapies to patients with serious unmet needs in liver cancer and psoriasis."

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 commenced a pivotal Phase III trial. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in 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. For example, the Company is using forward-looking statements when it discusses the completion of the offerings, the satisfaction of customary closing conditions related to the offerings and the intended use of proceeds therefrom. 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 market and other conditions, 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 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 April 14, 2025 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
