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 March 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 ☐

The first paragraph of the press release attached hereto as Exhibit 99.1 is 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. 333-236064, 333-274316, 333-262055, 333-276000 and 333-281872), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 March 19, 2025, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite to Initiate Phase II Study in the Rare Genetic Disease Lowe Syndrome with Piclidenoson" A copy of this press release is furnished herewith as Exhibit 99.1.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated March 19, 2025

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: March 19, 2025

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

Exhibit 99.1

Can-Fite to Initiate Phase II Study in the Rare Genetic Disease Lowe Syndrome with Piclidenoson

FDA & EMA approvals for rare genetic diseases are fast and require clinical studies with small number of patients

Ramat Gan, Israel, March 19, 2025 -- 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 a Phase II design is completed and preparatory work is undergoing for the initiation of clinical study in the rare genetic disease Lowe Syndrome.

Dr. Franchesca Emma from the Division of Nephrology, Bambino Gesù Children's Hospital - IRCCS Rome Italy, will be the principal investigator of the study. The Phase II open study will enroll 5 patients that will be treated twice daily with 3 mg Piclidenoson for 12 months. The study's primary end point will be the efficacy of Piclidenoson in increasing 99mTc-DMSA renal uptake.

The treatment of this rare genetic disease is based on successful pre-clinical work of Dr. Antonella De Matteis, Professor of Biology, Department of Molecular Medicine and Medical Biotechnology at the University of Naples Federico II, and Program Coordinator of the Cell Biology and Disease Mechanisms at the Telethon Institute of Genetics and Medicine (TIGEM) in Italy. Can-Fite and Fondazione Telethon have signed a collaboration agreement for the clinical development of Piclidenoson for the treatment of Lowe Syndrome, a high medical need with no drug available.

Lowe Syndrome, also known as oculo-cerebro- renal syndrome (OCRL), an X-linked genetic condition occurring almost exclusively in males, is a multisystem disorder characterized by vision problems including clouding of the lenses of the eyes (cataracts) that are present at birth, kidney problems (consisting of urinary loss of proteins and solutes) that usually develop in the first year of life, and brain abnormalities associated with intellectual disabilities, and a life span that rarely exceeds 40 years. Lowe Syndrome prevalence is estimated at approximately 1 in 500,000.

"Having tested thousands of compounds in search of a treatment for Lowe Syndrome, Piclidenoson is the only compound we've found to date that has shown to be effective in pre-clinical studies. Importantly, we observed that Piclidenoson treatment in preclinical models of Lowe syndrome leads to a significant decrease of the urinary loss of proteins," Dr. De Matteis stated. "We chose to investigate Piclidenoson based on the availability of extensive scientific data showing its excellent safety, coupled with efficacy in this disease in pre-clinical studies which involves renal, cerebral, and ocular manifestations."

Can-Fite CSO&Chairperson Dr. Pnina Fishman commented, "We are very much enthusiastic by the breakthrough research of Dr. De Matteis showing that Piclidenoson is efficacious in treating pre-clinical models of Lowe Syndrome. Her impressive results are the basis for implementing Piclidenoson in the treatment of this rare genetic disease". stated Dr. Pnina Fishman, Can-Fite CSO & Chairperson".

About Piclidenoson

Piclidenoson is a robust anti-inflammatory agent, currently being evaluated in a pivotal Phase III psoriasis clinical study under approval of both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Piclidenoson is a novel, first-in-class, A3 adenosine receptor agonist (A3AR) small molecule, orally bioavailable drug with an excellent safety profile demonstrating evidence of efficacy in Phase II and Phase III clinical studies. The drug's mechanism of action entails inhibition of the inflammatory cytokines interleukin 17 and 23 (IL-17 and IL-23) and the induction of apoptosis of patients' skin cell keratinocytes involved with the disease pathogenicity.

About Fondazione Telethon

Fondazione Telethon ETS is one of the main Italian biomedical charities, founded in 1990 on the initiative of a group of patients suffering from muscular dystrophy. Its mission is to achieve the cure of rare genetic diseases through scientific research of excellence, selected according to the best practices shared internationally. Through a unique method in the Italian panorama, it follows the entire "research chain" dealing with fundraising, selection and funding of projects and the research activity itself carried out in the centers and laboratories of the Foundation. Telethon also develops collaborations with public health institutions and pharmaceutical industries to translate the results of research into therapies accessible to patients. Since its foundation, Telethon has invested more than 660 million euros in research, has funded 2,960 projects with 1,720 researchers involved and 630 diseases studied. To date, thanks to Fondazione Telethon, the first gene therapy with stem cells in the world has been made available, thanks to the collaboration with the pharmaceutical industry. This therapy is intended for the treatment of ADA-SCID, a severe immunodeficiency that compromises the body's defenses from birth. In 2023, Fondazione Telethon became responsible for the production and distribution of the drug to eligible patients in the European Union.

Another gene therapy resulting from Telethon research made available is the one for a serious neurodegenerative disease, metachromatic leukodystrophy. This therapeutic approach is in an advanced stage of development for another immunodeficiency, Wiskott-Aldrich syndrome. Other diseases on which the gene therapy developed by Telethon researchers has been evaluated in patients are beta thalassemia and two metabolic diseases of childhood, mucopolysaccharidosis type 6 and type 1. In addition, within the Telethon institutes a targeted therapeutic strategy is being studied or developed for other genetic diseases, such as hemophilia or various hereditary vision defects. In parallel, the study of basic mechanisms and potential therapeutic approaches for diseases still unanswered continues in all laboratories funded by Telethon.

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 and is expected to commence a pivotal Phase III. 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: https://www.canfite.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 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.

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