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 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 ☐

On September 24, 2024, Can-Fite BioPharma Ltd. issued a press release entitled “Projected Income of $325M to Can-Fite Over the Next 10 Years After Vetbiolix Exercised its Option and Licensed Piclidenoson for Veterinary Osteoarthritis.” A copy of this press release is furnished herewith as Exhibit 99.1.

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated September 24, 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: September 24, 2024

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

Exhibit 99.1

Projected Income of $325M to Can-Fite Over the Next 10 Years After Vetbiolix Exercised its Option and Licensed Piclidenoson for Veterinary Osteoarthritis

The agreement has been signed upon successful conclusion of a clinical study in dogs with osteoarthritis

RAMAT GAN, Israel, Sept. 24, 2024 (GLOBE NEWSWIRE) -- 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 announced that its veterinary partner Vetbiolix exercised its option and signed a development and commercialization agreement with Can-Fite for the development of Piclidenoson for the treatment of osteoarthritis in companion animals including dogs and cats.

Vetbiolix concluded successfully a clinical study in dogs with osteoarthritis who were treated orally with piclidenoson for a couple of months period. The arthritis market for companion animals is estimated by Coherent Market Insights to be $3.8 Billion in 2023 and is expected to grow to $6.3 Billion by 2030. Can-Fite and Vetbiolix model that Piclidenoson has the potential to capture up to 6% of this opportunity, with peak worldwide sales of $445 Million by 2034. Under the agreement, Can-Fite is entitled to receive a 15% royalty on worldwide sales in this indication. This means that Can-Fite's upfront and royalties on sales upon regulatory approval for veterinary use, is projected to be $325 million in the aggregate over the next decade assuming a 2027 launch.

Current treatments for canine osteoarthritis include oral non-steroidal anti-inflammatory drugs (NSAIDs) which only treat symptoms and carry significant harmful side effects, and an injectable disease modifying osteoarthritis drug (DMOAD) that targets the progression of the disease. Piclidenoson, an oral drug that has a favorable safety profile in humans and in animal studies, offers a potentially safe and effective oral treatment for canine osteoarthritis.

"The veterinary market is a significant opportunity where our drugs may have an impact. Both the size of the market and the shorter timelines to regulatory approval have the potential to result in milestone and royalty revenues for Can-Fite. We believe Piclidenoson's safety and efficacy data in dogs indicate it may offer relief to the growing number of companion animals with osteoarthritis," stated Can-Fite VP Business Development Dr. Sari Fishman.

Matthieu Roquette, President at Vetbiolix commented, "The quality of preclinical and clinical data generated by us on Piclidenoson, and its pharmacological profile make this highly selective A3 Adenosine Receptor Agonist a drug candidate likely to meet the unmet veterinary medical need to date in the management of osteoarthritis pathology in dogs and cats."

On top of the U.S. Can-Fite patent #10,265,337 Vetbiolix applied for additional new patent applications based on the new data from the dog clinical study that has been concluded recently.

About Vetbiolix

Vetbiolix develops innovative products for treatment and prevention of diseases affecting pets. As pharmaceutical and biotech companies research novel molecules and compounds for human medicine, tests in different species often reveal exciting possibilities for pets. Vetbiolix has developed a unique approach focused on turning this potential into innovative prescription medicines and care products for pets. To date, veterinarians have still few therapeutics and real preventive care products at their disposal that have been specifically developed and approved for pets. Along with a virtual VetBiotech organization, Vetbiolix exclusively focuses on clinical developments of prescription medicines, diagnostics, nutraceuticals and care products for pets, thanks to its qualified external R&D partners in Europe & the US. Vetbiolix is supported by the Eurasanté Bio-Incubator, the northern France health cluster ranked among the top 20 best European incubators fostering pharm/biotech start-up development (Labiotech.eu 2019).

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.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, revenue projections, 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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