

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 August 2022

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

The first two paragraphs of the press release attached to this Form 6-K are hereby incorporated by reference into the registrant's Registration Statements on [Form S-8](#) (File No. 333-227753) and Form F-3 (File Nos. [333-195124](#), [333-236064](#), [333-249063](#) and [333-262055](#)), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 August 17, 2022, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite: Reports Progress in the Development of Piclidenoson for Osteoarthritis in Pets Through its Partner Vetbiolix". A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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Exhibit Index

Exhibit No.	Description
99.1	Press Release dated August 17, 2022

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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: August 17, 2022

By: /s/ Pnina Fishman
Pnina Fishman
Chief Executive Officer

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Can-Fite: Reports Progress in the Development of Piclidenoson for Osteoarthritis in Pets Through its Partner Vetbiolix

- *Safety study successfully completed; efficacy trial to commence and financially covered by Vetbiolix*
- *Canine osteoarthritis market is projected to reach \$3 billion by 2028*

PETACH TIKVA, Israel, August 17, 2022 -- 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, announced today that through a development and commercialization agreement signed with Vetbiolix in June of 2021, Piclidenoson is set to enter a clinical trial for the treatment of osteoarthritis in dogs. The canine osteoarthritis market is projected to reach \$3 billion by 2028.

Vetbiolix, a France-based veterinary biotech company, which has the exclusive right to Piclidenoson in the veterinary osteoarthritis market for companion animals including cats and dogs for two years, recently completed an initial study in dogs to explore dose-range safety and pharmacokinetics. Piclidenoson was well tolerated, with the pharmacokinetic data proportional to dose. Based on these data, Vetbiolix is moving forward with clinical safety and efficacy studies in dogs with osteoarthritis.

If the study yields positive data and Vetbiolix exercises its option to obtain the license from Can-Fite, then Vetbiolix will be obligated to pay Can-Fite upfront and milestone payments, in addition to royalties on sales upon regulatory approval.

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.

“We have had a highly productive collaboration with Vetbiolix and are very pleased that they are moving Piclidenoson forward into clinical efficacy studies in dogs with osteoarthritis,” stated Can-Fite CEO Dr. Fishman. “We are hopeful that Piclidenoson, with its excellent safety and efficacy profile in human auto-immune disease, will also provide an effective treatment for canines with osteoarthritis resulting in greater quality of life for dogs and their human families.”

About Piclidenoson

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 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 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. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of non-alcoholic steatohepatitis (NASH), and enrollment is expected to commence in a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver 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 1,500 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, market risks and uncertainties, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. 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. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite’s authorized executive officers. 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 risks and uncertainties that could cause Can-Fite’s actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite’s actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: 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 impact of the COVID-19 pandemic; 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; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed in Can-Fite’s filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

Contact

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