

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 June 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): ____

On June 24, 2022, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite's CF602 Reverses Erectile Dysfunction in Diabetic Pre-clinical Model: Study Published in Peer-Reviewed Journal Andrologia". 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 June 24, 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: June 24, 2022

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

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Can-Fite's CF602 Reverses Erectile Dysfunction in Diabetic Pre-clinical Model: Study Published in Peer-Reviewed Journal *Andrologia*

- *CF602's unique mechanism of action enables potential treatment of diabetic patients and may offer an alternative to PDE5 (Viagra, Cialis, Levitra, and Stendra) non-responders accounting for 30-35% of the \$3.6 billion ED market*
- *Patents granted in numerous healthcare markets including the U.S., Australia, and Japan*

PETACH TIKVA, Israel, June 24, 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, today announced its study titled "A3 adenosine receptor allosteric modulator CF602 reverses erectile dysfunction in a diabetic rat model" was published in the peer-reviewed journal *Andrologia*.

A full erectile recovery was achieved following a single dose of CF602 with restored muscle collagen ratio and endothelial cell function. Can-Fite's CF602, an allosteric modulator of the A3 adenosine receptor (A3AR), applied topically or orally in a diabetic rat model, resulted in increased arterial blood flow and significant dose-dependent improvements in intracavernosal pressure (ICM), smooth muscle:collagen ratio, vascular endothelial growth factor and endothelial nitric oxide synthase.

While oral phosphodiesterase type 5 (PDE5) inhibitors are the current standard of care for erectile dysfunction (ED), with brands including Viagra, Cialis, Levitra, and Stendra, an estimated 30% to 35% of ED patients are non-responders, and these drugs can be contraindicated for people living with diabetes.

Data published in the article suggest CF602 could potentially offer an alternative treatment to PDE5 inhibitors, particularly to PDE5 non-responders and diabetics.

"There is a clear and unmet need in the market today for an effective alternative to PDE5 inhibitors for non-responders to the leading sexual dysfunction drugs and diabetics, many of whom cannot safely be prescribed PDE5 inhibitors. With a growing body of data and IP estate around CF602, we are evaluating potential strategic partnerships to advance CF602 toward market," stated Can-Fite CEO Dr. Pnina Fishman.

According to Zion Market Research, the global ED market was valued at \$3.64 billion in 2021 and is projected to reach \$5.94 billion by 2028.

About CF602

CF602 is a novel A3AR allosteric modulator that enhances the receptor activity in the presence of the native ligand. The molecule is characterized by high selectivity at the A3AR and is capable of avoiding receptor desensitization, thus magnifying the agonist activity at low doses.

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 has completed enrollment 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 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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