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 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 ☐

The first, second and third paragraphs of the press release attached to this Form 6-K 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. 333-195124, 333-236064, 333-249063, 333-262055 and 333-276000), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 May 6, 2024, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Received Notice of Allowance from the European Patent Office for the Treatment of Erectile Dysfunction with CF602". A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated May 6, 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: May 6, 2024

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

Exhibit 99.1

Can-Fite Received Notice of Allowance from the European Patent Office for the Treatment of Erectile Dysfunction with CF602

Patent has already been issued in other major markets including the U.S.

PETACH TIKVA, Israel, May 06, 2024 -- 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 it received a Notice of Allowance from the European Patent Office for its patent application titled "An A3 Adenosine Receptor Ligands For Use in Treatment of a Sexual Dysfunction". This invention addresses the use of the CF602 drug candidate as an oral or topical drug for patients such as diabetics, who suffer from erectile dysfunction, and cannot use the current drugs on the market.

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.

Can-Fite recently published an article in*Andrologia*, suggesting that CF602 could potentially offer an alternative to the current drugs on market. 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. treatment to PDE5 inhibitors, particularly to PDE5 non-responders and diabetics.

"This additional European patent for erectile dysfunction adds to our growing IP estate for this high-value indication of the CF602 drug candidate. We believe our strong and broad IP, together with the pre-clinical positive data position it as a promising candidate for further development for the treatment of sexual dysfunction," stated Motti Farbstein, Can-Fite CEO.

The Erectile Dysfunction market is expected to reach approximately $6.6 billion by 2030, according to Market Research Future.

About Namodenoson

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson is currently being evaluated in a pivotal Phase III trial for advanced liver cancer, a Phase IIb trial for the treatment of steatotic liver disease (SLD), and the Company is planning a Phase IIa study in pancreatic cancer. A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential expression may be one of the important factors that accounts for the excellent safety profile of the drug.

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 is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment metabolic dysfunction-associated steatohepatitis (MASH), a Phase III pivotal 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.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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