
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 2020

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 paragraph 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 No. 333-227753) and Form F-3 (File Nos. 333-195124, 333-204795, 333-209037 and 333-220644), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 3, 2020, Can-Fite BioPharma Ltd. issued a press release announcing it is submitting its annual Drug Safety Update Reports (DSUR) for both Piclidenoson and Namodenoson to the governing health regulatory agencies where its drug candidates are currently treating patients. 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 March 3, 2020 |

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 3, 2020

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

Can-Fite is filing Drug Safety Update Report Showing Positive Safety Results from Phase II and Phase III Studies of Namodenoson and Piclidenoson

Favorable safety profile is a substantial benefit in the treatment of chronic diseases that require long-term dosing

PETACH TIKVA, Israel, March 03, 2020 -- [Can-Fite BioPharma Ltd.](#) (NYSE American: CANF) (TASE:CFBI), a biopharmaceutical company with a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced it is submitting its annual Drug Safety Update Reports (DSUR) for both Piclidenoson and Namodenoson to the governing health regulatory agencies where its drug candidates are currently treating patients. Submission of the DSUR is an annual requirement for investigational-stage new drugs under development in territories which subscribe to the International Council for Harmonization guidelines, including the U.S. Food and Drug Administration and the European Medicines Agency. The DSUR includes updates on drug safety information such as adverse events, suspected unexpected serious adverse reactions, and other indicators of potential risk. Can-Fite's reports being filed this year extend the growing body of documentation showing both Piclidenoson and Namodenoson have favorable safety profiles and risk-benefit ratios in more than 1500 patients.

Dr. Michael Silverman, M.D., Can-Fite's Medical Director, commented, "We welcome the opportunity to compile our cumulative data on a regular basis, as afforded by the DSUR process. As in years past, these snapshots of our safety data continue to confirm that both of our A3AR drugs in development are well-tolerated. We are pleased that there are no emerging safety concerns that could put patients at risk or impede our efforts to develop new drugs to meet unmet patient needs. These latest data are particularly robust, as we have achieved over 50% enrollment in both of our Phase III studies for Piclidenoson, as well as having completed two Phase II trials for Namodenoson."

Piclidenoson is currently in two Phase III studies, one for the treatment of moderate-to-severe psoriasis to establish superiority versus placebo and non-inferiority versus Otezla® with over 50% of the planned 407 patients already enrolled; and another for the treatment of moderate-to-severe rheumatoid arthritis in newly diagnosed patients to establish non-inferiority to MTX, the standard of care, with over 50% of the planned 500 patients enrolled and an interim analysis is planned. Namodenoson has completed a 78-patient Phase II study in liver cancer and Can-Fite is currently preparing for a Phase III trial in this indication. Namodenoson has also recently completed enrollment in a 60 patient Phase II study in the treatment of NASH, with topline results expected in later this month.

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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is in a Phase II trial for the treatment of non-alcoholic steatohepatitis (NASH). 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 1,000 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 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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