
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 December 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 and second 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, 333-209037 and 333-249063), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 December 15, 2020, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite Receives Israel Ministry of Health Approval to Conduct Research with Cannabinoids in Cancer, Inflammation and Obesity at the Company Discovery Labs”. 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 December 15, 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: December 15, 2020

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

Can-Fite Receives Israel Ministry of Health Approval to Conduct Research with Cannabinoids in Cancer, Inflammation and Obesity at the Company Discovery Labs

- *State-of-the-art in house labs leveraged for cost and time efficient development of high-value cannabinoid assets*
- *Cannabinoids bind to A3 adenosine receptor (A3AR), which is over-expressed in pathological cells and is the target of Can-Fite's technology platform*
- *Company has patent pending for cannabinoids in the treatment of diseases through its A3 adenosine receptor (A3AR) technology platform*

PETACH TIKVA, Israel, December 15, 2020 -- 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 it has received approval from the Medical Cannabis Unit of Israel's Ministry of Health to conduct pre-clinical studies on the effect of nanomolar concentrations of cannabinoid fractions on the proliferation and functionality of cancer, inflammatory and adipocyte cells (fat cells).

This regulatory approval clears Can-Fite to advance its cannabinoid program by evaluating the effect of cannabis fractions at nanomolar concentrations binding with the A3 adenosine receptor (A3AR), the target of the Company's technology, in a broad range of diseases including cancer, inflammatory diseases, and metabolic diseases associated with fat accumulation. Can-Fite's recent findings show that cannabinoids can be clinically effective at minute concentrations, thereby potentially delivering efficacy without the adverse effect seen to occur with high cannabinoid concentrations as evidenced in the scientific literature. Prior pre-clinical studies jointly conducted by Can-Fite and Univo Pharmaceuticals demonstrate cannabinoid fractions inhibited liver cancer cell proliferation via A3AR.

"We are excited to embark on research to advance our cannabinoids program, which leverages our current IP platform, technology, and discovery lab assets to cost-and-time-efficiently generate findings in one of the fastest growing and promising areas in the pharmaceutical space. As a world leader in A3AR, Can-Fite is ideally positioned to identify and develop cannabinoids at nanomolar concentrations to treat diseases effectively and safely," stated Can-Fite CEO Dr. Pnina Fishman.

Can-Fite will conduct the research in its own state-of-the-art discovery labs where it recently developed patent-pending cannabinoid-based formulations and an in vitro biological assay to identify clinically active cannabis derived compounds. The Company's recently filed patent application covers the use of cannabinoids in treating A3AR associated conditions including cancer, autoimmune, inflammatory, and metabolic diseases. Can-Fite's biological cell-based assay will be utilized in the development of pharmaceuticals that use a specific cannabis derived compound to treat a variety of diseases. In addition to benefitting from its assay in the development of its own cannabis derived compound-based therapeutics, Can-Fite plans to market the assay on a 'fee for service' basis to researchers and other cannabis companies worldwide.

According to Adroit Market Research, the medical cannabis market is projected to grow at a CAGR of 29% to \$56.7 billion by 2026.

Can-Fite has a strategic partnership with Univo Pharmaceuticals, a medical cannabis company.

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, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint 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 1,500 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

Can-Fite BioPharma

Motti Farbstein

info@canfite.com

+972-3-9241114
