
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 November 2023

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 ☐

On November 1, 2023, Can-Fite BioPharma Ltd. issued a press release entitled “Can-Fite Issues Business Update: All Clinical Programs and Business Development Activities Remain Solidly on Track”. 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 November 1, 2023

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: November 1, 2023

By:  /s/ Motti Farbstein

Motti Farbstein

Chief Executive Officer and Chief Financial Officer

Can-Fite Issues Business Update: All Clinical Programs and Business Development Activities Remain Solidly on Track***Company management updates about ongoing activities and progress***

PETACH TIKVA, Israel, November 01, 2023 -- 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 confirmed that all of the Company's clinical and business development activities are ongoing and proceeding by both its Israeli and US based staff.

"Can-Fite remains focused and stronger than ever in our purpose to bring medications to market that improve and save lives. We are working closely with our US based executives, Dr. Bill Kerns and Dr. Michael Silverman, with all our consultants and our collaboration partners in Canada, Europe, the US, China and South Korea. All the investigators participating in the conductance of the clinical studies are working full force and continue patient enrolment for the ongoing advanced clinical studies," stated Dr. Pnina Fishman, Can-Fite's Chief Scientific Officer and Executive Chairman. "Our business development activities are robust and we are receiving a high level of interest, in both Namodenoson and Piclidenoson, which we believe may lead to new pharma partnerships in the near-term."

The Company's advanced-stage clinical pipeline includes two pivotal Phase III studies: an ongoing trial in advanced liver cancer and a psoriasis study that has been cleared by the U.S. Food and Drug Administration as well as the European Medicines Agency and is expected to commence enrollment shortly. Phase II trials include an ongoing study for steatotic liver disease (SLD), formerly known as NASH, and preparatory work is underway for a Phase IIa trial in pancreatic cancer.

Can-Fite's latest value-driving developments include its entry into the rare genetic diseases market with Piclidenoson which was found to be effective in pre-clinical studies for the treatment of Lowe Syndrome, an estimated \$100 million treatment market in the U.S. alone in which there is no therapeutic treatment option available. Through a partnership with Collaborations Pharmaceuticals, Can-Fite will now utilize artificial intelligence (AI) and machine learning (ML) techniques to identify next-generation A3 adenosine receptor drug agonists and significantly reduce development time and costs of bringing such drugs to market.

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 of steatotic liver disease (SLD), 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.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, 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 the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and security, political and economic instability in the Middle East that could harm our business, including due to the current war between Israel and Hama. 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 30, 2023 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.

Contact

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