

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 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): ____

This Report on Form 6-K (including the text under the heading "Financial Results", the accompanying interim condensed consolidated financial statements and "Forward-Looking Statements" in the press release in Exhibit 99.1) 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](#), [333-236064](#), [333-209037](#), [333-249063](#) and [333-262055](#)), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 26, 2022, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Reports First Quarter 2022 Financial Results & Provides Clinical Update". 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 26, 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: May 26, 2022

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

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Can-Fite Reports First Quarter 2022 Financial Results & Provides Clinical Update

PETACH TIKVA, Israel, May 26, 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 financial results for the quarter ended March 31, 2022.

Corporate and Clinical Development Highlights Include:

Fortified Balance Sheet - On March 31, 2022, Can-Fite had approximately \$16.5 million in cash, cash equivalents, and short-term deposits.

Phase III Psoriasis Study Data Expected Q2 2022 – Topline results are expected in Q2 2022 in Can-Fite’s Phase III Comfort™ psoriasis study for both its 16 week primary endpoint and 32 week secondary endpoint. The study is designed to establish Piclidenoson’s superiority compared to placebo at 16 weeks and non-inferiority compared to Apremilast (Otezla®) at 32 weeks. During the first quarter, a preclinical study showed Piclidenoson destroyed pathological skin cells, offering further evidence of potential efficacy in psoriasis.

Developing Topical Psoriasis Treatment - In a preclinical model, daily treatment with topical Piclidenoson significantly inhibited psoriasis as measured by the psoriasis area severity index (PASI) calculated based on observation of erythema, thickness, scaling, and a score of skin lesions. The topical treatment may serve as a complementary product to oral Piclidenoson.

Commenced Enrollment in Phase IIb NASH Study– In January, Can-Fite enrolled the first patient in its Phase IIb multicenter, randomized, double-blind, placebo-controlled study in 140 subjects with biopsy-confirmed NASH. The primary objective of the trial is to evaluate the efficacy of Namodenoson as compared to placebo as determined by a histological endpoint. In a prior Phase IIa study, Namodenoson met its primary endpoint by reducing liver fat, inhibiting fibrosis, and demonstrating an anti-inflammatory effect.

Granted U.S. Patent for Liver Fibrosis and Israeli Patent for NASH –The U.S. Patent and Trademark Office granted Can-Fite a patent for its invention titled “Method for Treating Fibrotic Liver Tissue Using CL-IB MECA”, a broad patent that addresses markets for the treatment of all advanced liver fibrosis indications. The patent opens an opportunity for much broader market needs which entail all clinical conditions with advanced liver fibrosis including autoimmune hepatitis, primary biliary cirrhosis (PBC), nonalcoholic fatty liver disease (NAFLD), and alcoholic liver disease (ALD) among others. The Israel Patent Office granted Can-Fite a patent titled “An A3 Adenosine Receptor Ligand For Use In Treating Ectopic Fat Accumulation” which has been issued in approximately 40 other countries.

Opened Enrollment in Pivotal Phase III Liver Cancer Study– Can-Fite’s pivotal Phase III liver cancer study for Namodenoson opened for enrollment of approximately 450 patients diagnosed with hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to other approved therapies. An interim analysis will be conducted after 50% of patients are enrolled and treated. The primary endpoint is overall survival. Can-Fite has received Orphan Drug Designation in both the U.S. and Europe and has received the U.S. FDA’s Fast Track Status.

Presented Data on Cannabinoids in the Treatment of Liver Cancer at CannX– In March, Can-Fite delivered a presentation titled “Inhibition of Hepatocellular Carcinoma Growth and Liver Fibrosis by Nanomolar Cannabinoids Concentrations” at the CannX Medical Cannabis Conference in Tel Aviv. The findings were also published in the peer-reviewed scientific journal *Medical Cannabis and Cannabinoids* highlighting the ability of CBD-rich T3/C15 in nanomolar concentrations to inhibit the growth of hepatocellular carcinoma and liver stellate cells via A3AR activation and deregulation of the Wnt/β-catenin pathway.

“We look forward to announcing Phase III psoriasis results before the end of the second quarter as we enroll patients in our other advanced stage clinical trials for NASH and liver cancer,” stated Can-Fite CEO Dr. Pnina Fishman. “Can-Fite is financially well positioned to conduct all our clinical development programs over the next year, and we continue to evaluate potential new distribution partnerships which may provide additional non-dilutive funding.”

Financial Results

Revenues for the three months ended March 31, 2022 were \$0.20 million, an increase of \$0.05 million, or 38.5%, compared to \$0.15 million for the three months ended March 31, 2021. The increase in revenues was mainly due to the recognition of a higher portion of advance payments received under a distribution agreement with Ewopharma than the advance payment received at the end of the first quarter of 2021.

Research and development expenses for the three months ended March 31, 2022 were \$1.82 million, an increase of \$0.52 million, or 39.8%, compared to \$1.30 million for the three months ended March 31, 2021. Research and development expenses for the first quarter of 2022 comprised primarily of expenses associated with an ongoing Phase III study of Piclidenoson for the treatment of psoriasis and two studies for Namodenoson, a Phase III study in the treatment of liver cancer and a Phase IIb study for NASH. The increase is primarily due to costs incurred in the first quarter of 2022 associated with the two new studies for Namodenoson.

General and administrative expenses for the three months ended March 31, 2022 were \$0.75 million a decrease of \$0.26 million, or 25.8%, compared to \$1.01 million for the three months ended March 31, 2021. The decrease is primarily due to the decrease in professional services for public relations and investor relations. We expect that general and administrative expenses will remain at the same level through 2022.

Financial expenses, net for the three months ended March 31, 2022 were \$0.06 million compared to finance income, net of \$0.29 million for the three months ended March 31, 2021. The decrease in financial income, net was mainly due to revaluation of our short-term investment which in 2021 was recorded as income and in 2022 was recorded as expense.

Net loss for the three months ended March 31, 2022 was \$2.43 million compared with a net loss of \$1.87 million for the three months ended March 31, 2021. The increase in net loss for the three months ended March 31, 2022 was primarily attributable to an increase in research and development expenses which was partly offset by a decrease in general and administrative expenses and a decrease in finance income, net.

As of March 31, 2022, Can-Fite had cash and cash equivalents and short term deposits of \$16.5 million as compared to \$18.9 million at December 31, 2021. The decrease in cash during the three months ended March 31, 2022 is due to the ongoing operation of the Company.

The Company’s consolidated financial results for the three months ended March 31, 2022 are presented in accordance with US GAAP Reporting Standards.

U.S dollars in thousands (except for share and per share data)

	<u>March 31, 2022</u> <u>Unaudited</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 5,504	\$ 4,390
Short term deposit	11,016	14,512
Prepaid expenses and other current assets	971	929
Short-term investment	182	237
<u>Total current assets</u>	<u>17,673</u>	<u>20,068</u>
NON-CURRENT ASSETS:		
Operating lease right of use assets	125	138
Property, plant and equipment, net	49	47
<u>Total long-term assets</u>	<u>174</u>	<u>185</u>
<u>Total assets</u>	<u>\$ 17,487</u>	<u>\$ 20,253</u>

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CONSOLIDATED BALANCE SHEETS

U.S dollars in thousands (except for share and per share data)

	<u>March 31,</u> <u>2022</u> <u>Unaudited</u>	<u>December 31,</u> <u>2021</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 1,124	\$ 954
Current maturity of operating lease liability	55	53
Deferred revenues	818	818
Other accounts payable	907	905
<u>Total current liabilities</u>	<u>2,904</u>	<u>2,730</u>
NON-CURRENT LIABILITIES:		
Long-term operating lease liability	54	71
Deferred revenues	2,865	3,070
<u>Total Long-term liabilities</u>	<u>2,919</u>	<u>3,141</u>
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.25 par value - Authorized: 5,000,000,000 shares at March 31, 2022 and December 31, 2021; Issued and outstanding: 815,746,293 shares as of March 31, 2022 and December 31, 2021	60,654	60,654
Additional paid-in capital	93,351	93,275
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(143,108)	(140,674)
<u>Total equity</u>	<u>12,024</u>	<u>14,382</u>
<u>Total liabilities and equity</u>	<u>\$ 17,847</u>	<u>\$ 20,253</u>

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S dollars in thousands (except for share and per share data)

	<u>Three months ended</u> <u>March 31,</u>	
	<u>2022</u>	<u>2021</u>
	<u>Unaudited</u>	
Revenues	\$ 205	\$ 148

Research and development expenses	(1,821)	(1,303)
General and administrative expenses	(754)	(1,016)
Operating loss	(2,370)	(2,171)
Total financial income (expense), net	(64)	293
Net loss	(2,434)	(1,878)
Basic and diluted net loss per share	(0.00)	(0.00)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	815,746,293	483,920,313

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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