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 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 March 30, 2023, Can-Fite BioPharma Ltd. issued a press release entitled "Can-Fite Reports 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 March 30, 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: March 30, 2023

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

Can-Fite Reports 2022 Financial Results & Provides Clinical Update

PETACH TIKVA, Israel, March 30, 2023 -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, today announced financial results for the year ended December 31, 2022.

2022 & Recent Corporate and Clinical Development Highlights Include:

PICLIDENOSON

Phase III COMFORT™ Psoriasis Trial Met Primary Endpoint – Patients receiving Piclidenoson 3mg demonstrated a statistically significant improvement when compared with placebo, as measured by the Psoriasis Area and Severity Index (PASI) 75 response at week 16 of treatment. An excellent safety profile was recorded.

Pivotal Phase III Psoriasis Registration Plan for Piclidenoson Submitted to EMA – Can-Fite submitted a market registration plan to the European Medicines Agency (EMA) for Piclidenoson in the treatment of moderate to severe psoriasis. A submission to the U.S. Food and Drug Administration (FDA) will follow.

Developing Piclidenoson as a Topical Psoriasis Treatment – In a preclinical model, daily treatment with topical Piclidenoson significantly inhibited psoriasis as measured by 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.

Piclidenoson Advances as a Treatment for Osteoarthritis in Dogs – Vetbiolix, Can-Fite's veterinary commercialization partner, achieved progress in the development of Piclidenoson for the canine osteoarthritis market projected to reach $3 billion by 2028. Vetbiolix is covering all costs associated with veterinary clinical development.

NAMODENOSON

Namodenoson Found to Significantly Inhibit Pancreatic Cancer in Preclinical Studies– Namodenoson was found to have a significant anti-cancer effect in pancreatic carcinoma as a monotherapy, as well as an additive effect when combined with gemcitabine, the standard-of-care chemotherapy for pancreatic cancer. Namodenoson's excellent safety profile and its ability to directly inhibit the growth of pancreatic tumors present its potential as an effective drug for the treatment of this disease which has a 5-year survival rate of only 11% in the U.S. Can-Fite has filed a patent application that covers the use of Namodenoson for the treatment of pancreatic cancer.

The U.S. Patent and Trademark Office Granted Can-Fite a Patent for the Treatment of Liver Fibrosis – The invention titled "Method for Treating Fibrotic Liver Tissue Using CL-IB MECA" is 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.

Ongoing Advanced Clinical Studies with Namodenoson:

- **Pivotal Phase III Liver Cancer Study for Namodenoson –**Can-Fite's pivotal Phase III liver cancer study for Namodenoson will enroll ~450 patients diagnosed with advanced hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to 1 or 2 other lines of therapy. The primary end point is overall survival. An interim analysis will be performed.

- **Phase IIb Namodenoson NASH Study** – 140 subjects with biopsy-confirmed NASH will be enrolled in the Phase IIb multicenter, randomized, double-blind, placebo-controlled study. 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.

Following Complete Response in a Patient with Advanced Liver Cancer Treated with Namodenoson:

- **Namodenoson Approved for Compassionate Use in Romania –** Romania became the second country, following Israel, to approve Namodenoson for compassionate use in patients with advanced liver cancer. Namodenoson induced a complete response with disappearance of all metastases in a patient who was enrolled in Can-Fite's prior Phase IIb liver cancer study. The patient is continuing treatment under the compassionate use program.

- **Patients with Decompensated Liver Cirrhosis Will Be Treated with Namodenoson Under Compassionate Use in Israel –** Patients with decompensated cirrhosis, an advanced form of cirrhosis associated with liver failure for which there are no therapeutic options other than liver transplantation, will be treated with Namodenoson at the Soroka Medical Center in Israel under compassionate use. Decompensated cirrhosis is an advanced form of cirrhosis associated with liver that impacts an estimated 10.6 million people globally.

"With two Phase III indications advancing through our pipeline, we look ahead to the potential commercialization of our small molecule drugs, Piclidenoson and Namodenoson," stated Can-Fite CEO Dr. Pnina Fishman. "Namodenoson in particular is showing the potential for efficacy across several indications from liver disease to pancreatic cancer. We remain focused and committed to bringing our safe, oral drugs to patients with unmet needs."

Financial Results

Revenues for the year ended December 31, 2022 were $0.81 million, a decrease of $0.04 million, or 4.7%, compared to revenues of $0.85 million during the twelve months ended December 31, 2021. The decrease is considered to be not material.

Research and development expenses for the year ended December 31, 2022 were $7.76 million, a decrease of $2.09 million, or 21.2%, compared to $9.85 million for the year ended December 31, 2021. Research and development expenses for the year ended December 31, 2022 comprised primarily of expenses associated with the completion of the Phase III study of Piclidenoson for the treatment of psoriasis and two ongoing studies for Namodenoson, a Phase III study in the treatment of advanced liver cancer and a Phase IIb study for NASH. The decrease is primarily due to the wrap up of the Phase III study of Piclidenoson for the treatment of psoriasis in 2022.

General and administrative expenses were $3.14 million for the year ended December 31, 2022, a decrease of $0.70 million, or 18.2%, compared to $3.84 million for the same period in 2021. The decrease is primarily due to the decrease in professional services and public and investor relations expenses. We expect general and administrative expenses will remain at the same level for 2023 and beyond.

Financial expense, net for the year ended December 31, 2022 was $0.07 million compared to financial income, net of $0.22 million for the same period in 2021. The decrease in financial income, net was mainly due to an increase in revaluation of our short-term investments which was offset by an increase in interest from short term deposits.

Can-Fite's net loss for the year ended December 31, 2022 was $10.17 million compared with a net loss of $12.61 million for the same period in 2021. The decrease in net loss was primarily attributable to a decrease in research and development expenses and a decrease in general and administrative expenses.

As of December 31, 2022, Can-Fite had cash, cash equivalents, and short-term deposits of $7.97 million as compared to $18.90 million at December 31, 2021. The decrease in cash during the year ended December 31, 2022 is due to Company's operating activity. During January 2023, the Company raised approximately $6.80 million net.

The Company's consolidated financial results for the twelve months ended December 31, 2022 are presented in accordance with US GAAP Reporting Standards.

More detailed information can be found in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2022, a copy of which has been filed with the Securities and Exchange Commission (SEC). The Annual Report, which contains the Company's audited consolidated financial statements, can be accessed on the SEC's website at http://www.sec.gov/ as well as via the Company's investor relations website at https://ir.canfite.com. The Company will deliver a hard copy of its Annual Report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Can-Fite Investor Relations at 10 Bareket Street, Kiryat Matalon, Petah-Tikva 4951778, Israel or by phone at +972-3-9241114.

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,978	$ 4,390
Short-term deposits	5,001	14,512
Prepaid expenses, and other current assets	1,170	929
Short-term investment	8	237
Total current assets	9,157	20,068
NON-CURRENT ASSETS:		
Operating lease right of use assets	84	138
Property, plant and equipment, net	42	47
Total non-current assets	126	185
Total assets	$ 9,283	$ 20,253

CONSOLIDATED BAL

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

	December 31,	
	2022	**2021**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 896	$ 954
Current maturity of operating lease liability	48	53
Deferred revenues	783	818
Other accounts payable	775	905
Total current liabilities	2,502	2,730
NON-CURRENT LIABILITIES:		
Long-term operating lease liability	14	71
Deferred revenues	2,295	3,070
Total non-current liabilities	2,309	3,141
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no par value - Authorized: 5,000,000,000 shares at December 31, 2022 and 2021; Issued and outstanding: 815,746,293 shares as of December 31, 2022 and 2021	-	-
Additional paid-in capital	154,192	153,929
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(150,847)	(140,674)

Total shareholders' equity	4,472	14,382
Total liabilities and shareholders' equity	$ 9,283	$ 20,253

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,		
	2022	**2021**	**2020**
Revenues	$ 810	$ 853	$ 763
Research and development expenses	(7,763)	(9,850)	(11,951)
General and administrative expenses	(3,143)	(3,845)	(2,951)
Operating loss	(10,096)	(12,842)	(14,139)
Total financial income (expense), net	(77)	227	(304)
Loss before taxes on income	(10,173)	(12,615)	(14,443)
Taxes on income	-	-	-
Net loss	$ (10,173)	$ (12,615)	$ (14,443)
Deemed dividend	-	(2,590)	(715)
Total comprehensive loss	$ (10,173)	$ (15,205)	$ (15,158)
Basic and diluted net loss per share	$ (0.01)	$ (0.03)	$ (0.04)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	815,746,293	553,079,638	358,411,297

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 recently reported topline results 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 enrollment is expected to commence in 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, 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 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 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.

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