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 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):☐

The text under the heading "Financial Results", the accompanying financial statements and "Forward Looking Statements" 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, 333-249063 and 333-262055), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 March 24, 2022, Can-Fite BioPharma Ltd. issued a press release announcing financial results for the year ended December 31, 2021. 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 24, 2022

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 24, 2022

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

Can-Fite Reports 2021 Financial Results & Provides Clinical Update

- ***Cash balance of $18.9 million as of December 31, 2021***
- **Signed out-licensing deal worth $42.7 million with Ewopharma**
- ***Phase III psoriasis topline data expected Q2 2022***
- ***Namodenoson induced complete response and cleared all cancer lesions in advanced liver cancer patient in Can-Fite's Phase II study***
- ***Phase IIb NASH study is currently enrolling patients***
- ***Pivotal Phase III advanced liver cancer study expected to commence enrollment for Namodenoson H1 2022***

PETACH TIKVA, Israel, March 24, 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 year ended December 31, 2021.

Corporate and Clinical Development Highlights Include:

Fortified Balance Sheet – On December 31, 2021, Can-Fite had $18.9 million in cash, cash equivalents, and short-term deposits. During the year, the Company received $2.25 million in non-dilutive funding from Ewopharma for an out-licensing deal, $2.74 million from warrant exercises, and raised $10 million through a registered direct offering.

Signed Deal Worth $42.7 Million with Ewopharma – In 2021, Can-Fite signed its largest out-licensing agreement to date with Switzerland-based Ewopharma for distribution of its drug candidates in Central Eastern Europe and Switzerland. A $2.25 million upfront payment was received with up to an additional $40.45 million payable upon the achievement of regulatory and sales milestones, plus 17.5% royalties on net sales. Together with Ewopharma, Can-Fite's existing out-licensing deals are worth a potential $130 million in future milestone payments plus double-digit royalties on net sales upon regulatory approvals. Can-Fite has received over $20 million in non-dilutive funding to date.

Liver Cancer Patient Completely Cleared of Cancer; Pivotal Phase III Liver Cancer Study Expected to Commence Enrollment H1 2022– A prior Phase II liver cancer study patient who continues to be treated with Namodenoson has survived five years and cleared all cancer lesions, in what the Company sees as a very positive sign for its upcoming pivotal Phase III liver cancer study. Enrollment is expected to commence H1 2022 with approximately 450 patients diagnosed with hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to other approved therapies.

Phase III Psoriasis Study Data Expected Q2 2022 – The Phase III Comfort™ study completed enrollment of >400 patients with moderate to severe plaque psoriasis and completed 16-weeks of treatment, the primary endpoint duration of the study. Topline results are expected in Q2 2022. 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. In a recently completed preclinical study, Piclidenoson destroyed pathological skin cells, offering further evidence of potential efficacy in psoriasis.

Phase IIb NASH Study Commenced Enrollment– This Phase II multicenter, randomized, double-blind, placebo-controlled study in subjects with biopsy-confirmed NASH enrolled its first patient in January. The primary objective of the trial is to evaluate the efficacy of Namodenoson as compared to placebo in 140 subjects with NASH, 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. There is currently no U.S. FDA approved treatment for NASH, an addressable pharmaceutical market estimated to reach $21.9 billion by 2028 driven by increasing incidence.

Several Patents Granted for Liver Diseases – Can-Fite's IP for Namodenoson in the treatment of liver diseases continues to grow. The Company was issued a Notice of Allowance in the U.S. for a broad patent that addresses markets for the treatment of all advanced liver fibrosis indications including NASH, NAFLD, autoimmune hepatitis, primary biliary cirrhosis, and more. Other patents specific to NASH and NAFLD were granted in 37 countries, most recently issued and allowed in Japan, Hong Kong, and Mexico.

A3AR-based Cannabis Compounds Found to Inhibit Liver Cancer Growth in Preclinical Study – Can-Fite continues to advance its findings for cannabinoids and its platform technology's target A3AR for which the Company has filed a patent. In 2021, Can-Fite completed pre-clinical studies demonstrating that a CBD rich T3/C15 cannabis fraction induces inhibition of liver cancer cell growth. These findings were published in peer-reviewed journals and presented at industry conferences.

"Our advanced-stage pipeline continues to achieve milestones, with Piclidenoson and Namodenoson both positioned as potentially safe and effective treatments for very large treatment indications including psoriasis, NASH, and liver cancer. In 2021 we signed our largest out-licensing deal to date, and in 2022 we anticipate additional new agreements as well as the potential of milestone payments from current agreements based on results from our current advanced stage trials," stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Revenues for the year ended December 31, 2021 were $0.85 million compared to revenues of $0.76 million during the twelve months ended December 31, 2020. The increase in revenues was mainly due to the recognition of a portion of an advance payment received under the Ewopharma distribution agreement entered in 2021 which was offset by the recognition of a lower portion of advance payments received under distribution agreements from Gebro, Chong Kun Dung Pharmaceuticals, and Cipher Pharmaceuticals.

Research and development expenses for the year ended December 31, 2021 were $9.85 million compared to $11.95 million for the year ended December 31, 2020. Research and development expenses in 2021 comprised primarily of expenses associated with two studies for Piclidenoson, a Phase III study in the treatment of psoriasis and a Phase II study in COVID-19 and Phase II studies for Namodenoson in the treatment of liver cancer and NASH. The decrease is primarily due to costs incurred in 2020 associated with the Univo research project which was completed by the end of that year and a Phase III study of Piclidenoson for the treatment of rheumatoid arthritis which was ongoing during 2020, partially offset by pre-clinical projects and the two ongoing studies of Piclidenoson. We expect research and development expenses will increase through 2022 and beyond.

General and administrative expenses were $3.84 million for the year ended December 31, 2021 compared to $2.95 million for the same period in 2020. The increase is primarily due to the increase in salaries and related benefits due to the distribution of bonuses to employees, increase in employee salaries, increase in public relations expenses, and insurance expenses. We expect general and administrative expenses will remain at the same level for the remainder of 2022 and beyond.

Financial income, net for the year ended December 31, 2021 was $0.23 million compared to financial expense, net of $0.3 million for the same period in 2020. The decrease in financial expense, net was mainly due to an increase in the revaluation of our short-term investment.

Can-Fite's net loss for the year ended December 31, 2021 was $12.6 million compared with a net loss of $14.4 million for the same period in 2020. The decrease in net loss was primarily attributable to a decrease in research and development expenses which were partly offset by an increase in general and administrative expenses and a decrease in finance income, net.

As of December 31, 2021, Can-Fite had cash, cash equivalents, and short-term deposits of $18.9 million as compared to $8.3 million at December 31, 2020. The increase in cash during the year ended December 31, 2021 is due to an aggregate of $2.74 million in net proceeds received through warrant exercise transactions during the first quarter of 2021, an advance payment of $2.25 million from a distribution agreement with Ewopharma and from a $10 million registered direct offering in August 2021 which were offset by the Company's operating activity.

The Company's consolidated financial results for the twelve months ended December 31, 2021 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, 2021, 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,	
	2021	**2020**
	USD	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,390	$ 8,268
Short-term deposits	14,512	-
Prepaid expenses, and other current assets	929	1,057
Short-term investment	237	75
Total current assets	20,068	9,400
NON-CURRENT ASSETS:		
Operating lease right of use assets	138	73
Property, plant and equipment, net	47	50
Total long-term assets	185	123
Total assets	$ 20,253	$ 9,523

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2021	**2020**
	USD	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 954	$ 561
Current maturity of operating lease liability	53	43
Deferred revenues	818	334
Other accounts payable	905	331
Total current liabilities	2,730	1,269
NON-CURRENT LIABILITIES:		
Long-term operating lease liability	71	24
Deferred revenues	3,070	2,156
Total Long-term liabilities	3,141	2,180
CONTIGENT LIABILITIES AND COMMITMENTS		

SHAREHOLDERS' EQUITY:		
Ordinary shares of NIS 0.25 par value - Authorized: 5,000,000,000 and 1,000,000,000 shares at December 31, 2021 and December 31, 2020, respectively; Issued and outstanding: 815,746,293 shares as of December 31, 2021; 463,769,463 shares as of December 31, 2020	60,654	33,036
Additional paid-in capital	93,275	97,380
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(140,674)	(125,469)
Total shareholders' equity	14,382	6,074
Total liabilities and shareholders' equity	$ 20,253	$ 9,523

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,		
	2021	2020	2019
	USD		
Revenues	$ 853	$ 763	$ 2,032
Research and development expenses	(9,850)	(11,951)	(10,976)
General and administrative expenses	(3,845)	(2,951)	(3,063)
Operating loss	(12,842)	(14,139)	(12,007)
Total financial income (expense), net	227	(304)	(618)
Loss before taxes on income	(12,615)	(14,443)	(12,625)
Taxes on income	-	-	-
Net loss	$ (12,615)	$ (14,443)	$ (12,625)
Deemed dividend	(2,590)	(715)	-
Total comprehensive loss	$ (15,205)	$ (15,158)	$ (12,625)
Basic and diluted net loss per share	$ (0.03)	$ (0.04)	$ (0.14)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	553,079,638	358,411,297	85,909,859

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 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, 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.

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