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Can-Fite Reports First Quarter 2021 Financial Results & Provides Clinical Update

PETACH TIKVA, Israel--(BUSINESS WIRE)-- 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, 2021.

Clinical Developments and Corporate Highlights Include:

Signed Large Out-licensing Deal Worth $42.7 Million with Ewopharma–During the first quarter, Can-Fite signed a large out-licensing agreement with Swiss-based Ewopharma for distribution of its drug candidates in Central Eastern Europe and Switzerland, receiving $2.25 million upfront 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.

Phase III Psoriasis Study Achieves 75% Enrollment– The Phase III Comfort™ study completed enrollment of 75% of planned patients for the study which is designed to establish Piclidenoson's superiority compared to placebo and non-inferiority compared to Apremilast (Otezla®) in patients with moderate to severe plaque psoriasis. The majority of costs associated with the Phase III Comfort™ study have been previously paid. The Company expects to complete enrollment in Q3 2021 and report topline results in Q4 2021.

Phase II COVID-19 Study Expands to Europe– Can-Fite is enrolling 40 patients hospitalized with moderate to severe COVID-19 in its Phase II study, under a U.S. Food and Drug Administration (FDA) approved protocol, in Israel and Europe.

Phase IIb NASH Study Expected to Commence Q4 2021– Based on a successfully concluded Phase IIa NASH/NAFLD study with Namodenoson which met its primary endpoint, Can-Fite completed the design of a Phase IIb study with the help of top NASH Key Opinion Leaders, Dr. Friedman and Dr. Harrison, and the Company plans to commence the Phase IIb study before the end of 2021.

Pivotal Phase III Liver Cancer Study Expected to Commence Q4 2021- Can-Fite is preparing to commence its pivotal Phase III trial for the treatment of hepatocellular carcinoma (HCC) based on a protocol agreed upon with the U.S. FDA and the European Medicines Agency. Should the study meet its efficacy endpoint and be approved by the FDA and EMA, Namodenoson would become one of only a few drugs available to treat advanced liver cancer patients. Recently announced data from Can-Fite's Phase II advanced liver cancer study included overall survival of 4 years in two patients. Additional findings show disappearance of ascites, normal liver function and good quality of life. A scientific paper

titled, “Namodenoson in Advanced Hepatocellular Carcinoma and Child–Pugh B Cirrhosis: Randomized Placebo-Controlled Clinical Trial” published in the peer reviewed journal *Cancers* provided more in-depth data from the Phase II study including a significant 12-month overall survival benefit in the CPB7 population, the target population for the pivotal Phase III study.

Cannabis Compounds May Have Role in Treatment of Liver Diseases- Can-Fite’s preclinical studies of cannabis compounds found CBD rich T3/C15 induced inhibition of liver cancer cell growth and also had an inhibitory effect on liver fibrosis. Liver fibrosis is associated with increased liver disease including NAFLD/NASH, cirrhosis, and liver cancer. Can-Fite has filed patent applications to protect its discovery of cannabinoid-based therapies where the A3AR target is overexpressed.

Topical CF602 Shows Preclinical Efficacy in Erectile Dysfunction (ED)– A new preclinical study of Can-Fite’s drug candidate CF602 in the treatment of ED in a diabetes experimental rat model showed that topically applied CF602 resulted in a statistically significant improvement in ED compared to controls. CF602 may be an ideal candidate for development due to topical efficacy, as ED is a common complication of diabetes and is difficult to treat with systemic drugs due to the high risk profile of these patients.

“Our robust advanced stage clinical pipeline, including a pivotal trial in liver cancer expected to commence in the fourth quarter, is supported by our growing number of global distribution agreements and accompanying non-dilutive funding,” stated Can-Fite CEO Dr. Pnina Fishman. “Recent efficacy findings in cannabis and ED create additional co-development and funding opportunities for Can-Fite with pharma partners.”

Financial Results

Revenues for the three months ended March 31, 2021 were $0.15 million, a decrease of $0.05 million, or 25.2%, compared to $0.20 million for the three months ended March 31, 2020. The decrease in revenues was mainly due to the recognition of a lower portion of advance payments received under distribution agreements from Gebro, Chong Kun Dung Pharmaceuticals, and Cipher Pharmaceuticals which were offset by the recognition of an advance payment portion received under a distribution agreement with Ewopharma.

Research and development expenses for the three months ended March 31, 2021 were $1.30 million, a decrease of $2.47 million, or 65.5%, compared to $3.77 million for the three months ended March 31, 2020. Research and development expenses for the first quarter of 2021 comprised primarily of expenses associated with two studies for Piclidenoson, a Phase II study in COVID-19 and a Phase III study in the treatment of psoriasis. The decrease is primarily due to costs incurred in the first quarter of 2020 associated with Phase II studies for Namodenoson in the treatment of liver cancer and NASH, and a Phase III study of Piclidenoson for the treatment of rheumatoid arthritis partially offset by the two ongoing studies of Piclidenoson in the first quarter of 2021. We expect that the research and development expenses will increase through 2021 and beyond.

General and administrative expenses for the three months ended March 31, 2021 were $1.01 million an increase of $0.31 million, or 44.5%, compared to $0.70 million for the three months ended March 31, 2020. The increase is primarily due to the increase in salaries and related benefits due to the distribution of bonuses to employees. We expect that general and

administrative expenses will remain at the same level through 2021.

Financial income, net for the three months ended March 31, 2021 were $0.3 million compared to finance expenses, net of $0.07 million for the three months ended March 31, 2020. The decrease in financial expense, net was mainly due to finance income recorded from revaluation of our short-term investment.

Net loss for the three months ended March 31, 2021 was $1.87 million compared with a net loss of $4.34 million for the three months ended March 31, 2020. The decrease in net loss for the three months ended March 31, 2021 was primarily attributable to a decrease in revenues in 2021, a decrease in research and development expenses which was partly offset by an increase in general and administrative expenses and a decrease in finance expenses, net.

As of March 31, 2021, Can-Fite had cash and cash equivalents and short term deposits of $11.24 million as compared to $8.26 million at December 31, 2020. The increase in cash during the three months ended March 31, 2021 is due to an aggregate of $2.74 million in net proceeds received through warrant exercises during the first quarter of 2021 and from an advance payment of $2.25 million from a distribution agreement with Ewopharma.

CONSOLIDATED BALANCE SHEETS

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

	March 31, 2021	December 31, 2020
	Unaudited	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,744	$ 8,268
Short term deposit	8,503	-
Other accounts receivables and prepaid expenses	1,016	1,057
Short-term investment	362	75
Total current assets	12,625	9,400
NON-CURRENT ASSETS:		
Right to use asset	63	73
Property, plant and equipment, net	54	50
Total long-term assets	117	123
Total assets	$ 12,742	$ 9,523

CONSOLIDATED BALANCE SHEETS

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

	March 31, 2021	December 31, 2020
	Unaudited	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 290	$ 561
Current maturity of operating lease liability	41	43
Deferred revenues	1,002	334
Other accounts payable	726	331
Total current liabilities	2,059	1,269
NON-CURRENT LIABILITIES:		
Long-term operating lease liability	14	24
Deferred revenues	3,591	2,156
Total Long-term liabilities	3,605	2,180
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.25 par value - Authorized: 500,000,000 shares at March 31, 2021 and December 31, 2020; Issued and outstanding: 515,746,293 shares as of March 31, 2021; 463,769,463 shares as of December 31, 2020	37,008	33,036
Additional paid-in capital	96,290	97,380
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(127,347)	(125,469)
Total equity	7,078	6,074
Total liabilities and equity	$ 12,742	$ 9,523

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Three months ended March 31,	
	2021	2020
	Unaudited	
Revenues	$ 148	$ 198

Research and development expenses	(1,303)	(3,771)
General and administrative expenses	(1,016)	(703)
Operating loss	(2,171)	(4,276)
Total financial income (expense), net	293	(66)
Net loss	(1,878)	(4,342)
Deemed dividend	-	(715)
Net loss attributed to ordinary shareholders	(1,878)	(5,057)
Basic and diluted net loss per share	(0.00)	(0.03)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	483,920,313	201,433,936

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.

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