November 26, 2021

Can-Fite Reports Third 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 September 30, 2021.

Corporate and Clinical Development Highlights Include:

Completed Patient Enrollment in Phase III Psoriasis Study– The Phase III Comfort™ study completed patient enrollment. Topline results are expected in Q1 2022. The study 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.

Can-Fite Ends Phase II COVID-19 Trial to Focus on Core Indications -In 2020, with the aim of developing a much-needed drug to treat manifestations of COVID-19, mainly the Cytokine Release Syndrome, Can-Fite initiated a Phase II COVID-19 study of its lead drug candidate, Piclidenoson, with patient enrollment in Israel and Europe. With the anticipated launch of Pfizer's oral COVID-19 antiviral drug candidate, Can-Fite has made a strategic decision to end its COVID-19 program and to focus its resources on its other clinical programs, all in advanced clinical trials.

Patents Granted for NASH in Japan, Hong Kong, and Mexico –Can-Fite continues to build its IP portfolio for NASH which now includes patents granted and allowed in 37 countries. Most recently, patents were issued and allowed in Japan, Hong Kong, and Mexico for the patent titled "An A3 Adenosine Receptor Ligand for Use In Treating Ectopic Fat Accumulation". This patent addresses the use of the A3 Adenosine Receptor (A3AR) ligand, the target receptor for Can-Fite's drug platform technology, in the treatment of NASH.

Data on A3AR-based Cannabis Compounds in the Treatment of Liver Diseases Presented at AASLD and Published in HEPATOLOGY – Can-Fite delivered a poster presentation titled "Growth Inhibition of Hepatocellular Carcinoma (HCC) by CBD Rich T3/C15 Cannabis Fraction is Mediated via the A3 Adenosine Receptor" at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® during the Hepatobiliary Neoplasia: Experimental Hepatocarcinogenesis; Diagnostics and Liver Imaging session. The findings were also published in an abstract in the October 2021 supplement of HEPATOLOGY, a premier peer-reviewed publication in the field of liver disease published on behalf of the AASLD.

Positive Phase IIa NASH Data Published in Alimentary Pharmacology & Therapeutics – The peer-reviewed scientific journal focused on gastroenterology and hepatology published an article titled "Randomised clinical trial: A phase 2 double-blind study of namodenoson in non-alcoholic fatty liver disease and steatohepatitis". The article includes

highlights from Can-Fite's Phase IIa NASH study of Namodenoson which achieved its study endpoints including significant anti-steatotic, anti-fibrotic, and anti-inflammatory effects.

Fortified Balance Sheet

On September 30, 2021, Can-Fite had approximately $13.3 million in cash, cash equivalents, and short-term deposits.

"Our NASH program has received a high level of interest at scientific conferences based on our positive Phase IIa results, and we continue to fortify our IP around this indication. We expect to commence enrollment in our pivotal Phase III liver cancer and Phase IIb NASH studies, as we look forward to topline results from our Phase III in psoriasis in the first quarter of 2022. Our advanced pipeline with a growing body of safety and efficacy data has significant potential to help patients with unmet needs," stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Revenues for the nine months ended September 30, 2021 were $0.65 million compared to revenues of $0.61 million during the nine months ended September 30, 2020. The increase is considered immaterial.

Research and development expenses for the nine months ended September 30, 2021 were $6.75 million compared with $9.06 million for the same period in 2020. Research and development expenses for the nine months period ended September 30, 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 nine months 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 nine months of 2021. We expect research and development expenses will increase for the remainder of 2021 and beyond.

General and administrative expenses were $2.71 million for the nine months ended September 30, 2021 compared to $2.14 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 public relations expenses and insurance expenses. We expect general and administrative expenses will remain at the same level for the remainder of 2021 and beyond.

Financial income, net for the nine months ended September 30, 2021 was $0.31 million compared to financial expense, net of $0.22 million for the same period in 2020. The decrease in financial expense, net was mainly due to finance income recorded from revaluation of our short-term investments.

Can-Fite's net loss for the nine months ended September 30, 2021 was $8.49 million compared with a net loss of $10.81 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 expenses, net.

As of September 30, 2021, Can-Fite had cash, cash equivalents and short-term deposits of $13.3 million as compared to $8.26 million at December 31, 2020. The increase in cash during the nine months ended September 30, 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 Company's operating activity.

The Company's consolidated financial results for the nine months ended September 30, 2021 are presented in accordance with US GAAP Reporting Standards.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	September 30, 2021 Unaudited	December 31, 2020 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,806	$ 8,268
Short-term deposits	7,503	-
Other receivable and prepaid expenses	811	1,057
Short-term investment	354	75
Total current assets	14,474	9,400
NON-CURRENT ASSETS:		
Operating lease right of use assets	116	73
Property, plant and equipment, net	49	50
Total long-term assets	165	123
Total assets	$ 14,639	$ 9,523

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	September 30, 2021	December 31, 2020

	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 806	$ 561
Current maturity of operating lease liability	40	43
Deferred revenues	1,002	334
Other accounts payable	305	331
Total current liabilities	2,153	1,269
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	62	24
Deferred revenues	3,090	2,156
Total long-term liabilities	3,152	2,180
CONTINGENT 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 September 30, 2021 and December 31, 2020, respectively; Issued and outstanding: 601,996,293 shares as of September 30, 2021; 463,769,463 shares as of December 31, 2020	43,716	33,036
Additional paid-in capital	98,457	97,380
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(133,966)	(125,469)
Total equity	9,334	6,074
Total liabilities and shareholders' equity	$ 14,639	$ 9,523

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Nine months ended September 30,	
	2021	**2020**

	Unaudited	
Revenues	$ 649	$ 613
Research and development expenses	(6,749)	(9,055)
General and administrative expenses	(2,714)	(2,144)
Operating loss	(8,814)	(10,586)
Total financial income (expenses), net	317	(224)
Net loss	(8,497)	(10,810)
Total comprehensive loss	(8,497)	(10,810)
Deemed dividend	-	(715)
Net loss attributed to ordinary shareholders	$ (8,497)	$ (11,525)
Basic and diluted net loss per share	(0.02)	(0.04)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	515,918,123	323,360,926

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 a Phase IIb 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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