August 26, 2021

Can-Fite Reports Second 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 June 30, 2021.

Corporate and Clinical Development Highlights Include:

Can-Fite Entered into Development and Commercialization Agreement in $3 Billion Veterinary Osteoarthritis Market – Can-Fite entered into a development and commercialization agreement with Vetbiolix, a France-based veterinary biotech company, for the development of Piclidenoson for the treatment of osteoarthritis in companion animals including dogs and cats. Vetbiolix will have the exclusive right to Piclidenoson in the veterinary osteoarthritis market for two years, during which time Vetbiolix will conduct proof-of-concept studies and cover all associated costs. If the studies yield positive data and Vetbiolix exercises its option to obtain the license from Can-Fite, then Vetbiolix will be obligated to pay Can-Fite upfront and milestone payments, in addition to royalties on sales upon regulatory approval for veterinary use. The canine osteoarthritis market is projected to reach $3 billion by 2024.

Can-Fite Received a Notice Allowance in China for itsNASH Patent - During the second quarter, Can-Fite received a Notice Allowance in China for its patent titled “An A3 Adenosine Receptor Ligand For Use In Treating Ectopic Fat Accumulation”. This patent, which has subsequently been issued to Can-Fite, addresses the use of the A3 Adenosine Receptor (A3AR) ligand, the target receptor for Can-Fite’s drug platform technology, to reduce liver fat particularly in patients with NASH.

Patent Filed for A3AR-based Cannabis Compounds in the 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, which is associated with 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.

Phase III Psoriasis Study Nears Completion of Enrollment– The Phase III Comfort™ study completed enrollment of 75% of planned patients during the second quarter, with full enrollment expected in the coming weeks. 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. Topline results are expected Q1 2022.

Phase II COVID-19 Study Expands into Europe– Can-Fite's ongoing Phase II study, under a U.S. FDA protocol, has been enrolling patients in Israel and expanded enrollment into Europe during the second quarter. The randomized, double blind, placebo-controlled study is evaluating the benefits of treatment with Piclidenoson plus standard supportive care (SSC) vs. placebo plus SSC in 40 patients hospitalized with moderate to severe COVID-19, as defined by the U.S. National Institutes of Health Coronavirus Disease 2019 (COVID-19) Treatment Guidelines.

Phase IIb NASH Study Receives Clearance from Israeli Ministry of Health– Can-Fite received clearance from the Israeli Ministry of Health to commence a Phase IIb study of its drug candidate Namodenoson in the treatment of NASH. Patient enrollment is expected to commence Q3 2021, ahead of the prior expected start date of Q4 2021. The Company expects to expand the study to additional clinical sites in Europe. A prior Phase IIa clinical trial of Namodenoson in the treatment of NASH met study endpoints showing anti-steatotic, anti-inflammatory, and anti-fibrotic effects.

Pivotal Phase III Liver Cancer Study Expected to Commence Q4 2021- Can-Fite has completed preparatory work for its pivotal Phase III study and plans to submit its study protocol and plans to Institutional Review Boards (IRBs) at potential clinical sites. The double blind, placebo-controlled trial will enroll 450 patients diagnosed with HCC and underlying Child Pugh B7 (CPB7) through clinical sites worldwide. Patients will be randomized to oral treatment with either 25 mg Namodenoson or matching placebo given twice daily. The primary efficacy endpoint of the trial is overall survival.

Fortified Balance Sheet

On June 30, 2021 Can-Fite had approximately $7.5 million in cash, cash equivalents, and short-term deposits. The Company closed an additional $10 million registered direct offering in August 2021.

"We expect multiple milestones in the coming months including topline results from our Phase III psoriasis study, in addition to the commencement of our pivotal Phase III in liver cancer and Phase IIb in NASH. We believe positive topline results may lead to further expansion of our global distribution strategy which has included significant non-dilutive funding," stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Revenues for the six months ended June 30, 2021 were $0.39 million compared to revenues of $0.40 million during the six months ended June 30, 2020. The decrease is considered immaterial.

Research and development expenses for the six months ended June 30, 2021 were $3.81 million compared with $7.05 million for the same period in 2020. Research and development expenses for the first half 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 six 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 six months of 2021. We

expect research and development expenses will increase through 2021 and beyond.

General and administrative expenses were $1.89 million for the six months ended June 30, 2021 compared to $1.45 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. We expect general and administrative expenses will remain at the same level through 2021.

Financial income, net for the six months ended June 30, 2021 was $0.20 million compared to financial expense, net of $0.12 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 investment.

Can-Fite's net loss for the six months ended June 30, 2021 was $5.09 million compared with a net loss of $8.23 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 June 30, 2021, Can-Fite had cash, cash equivalents and short-term deposits of $7.53 million as compared to $8.26 million at December 31, 2020. The decrease in cash during the six months ended June 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 and from an advance payment of $2.25 million from a distribution agreement with Ewopharma which were offset by Company’s operating activity.

The Company's consolidated financial results for the six months ended June 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)

	June 30, 2021 Unaudited	December 31, 2020 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,025	$ 8,268
Short-term deposits	6,512	-
Other receivable and prepaid expenses	1,745	1,057
Short-term investment	271	75
Total current assets	9,553	9,400
NON-CURRENT ASSETS:		

Operating lease right of use assets	77	73
Property, plant and equipment, net	50	50
Total long-term assets	127	123
Total assets	$ 9,680	$ 9,523

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2021 Unaudited	December 31, 2020 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,005	$ 561
Current maturity of operating lease liability	43	43
Deferred revenues	1,002	334
Other accounts payable	309	331
Total current liabilities	2,359	1,269
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	25	24
Deferred revenues	3,341	2.156
Total long-term liabilities	3,366	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 June 30, 2021 and December 31, 2020, respectively; Issued and outstanding: 515,746,293 shares as of June 30, 2021; 463,769,463 shares as of December 31, 2020	37,008	33,036
Additional paid-in capital	96,386	97,380
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(130,566)	(125,469)
Total equity	3,955	6,074
Total liabilities and shareholders' equity	$ 9,680	$ 9,523

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Six months ended June 30,	
	2021	2020
	Unaudited	
Revenues	$ 398	$ 402
Research and development expenses	(3,810)	(7,054)
General and administrative expenses	(1,892)	(1,455)
Operating loss	(5,304)	(8,107)
Total financial income (expenses), net	207	(128)
Net loss	(5,097)	(8,235)
Total comprehensive loss	(5,097)	(8,235)
Deemed dividend	-	(715)
Net loss attributed to ordinary shareholders	$ (5,097)	$ (8,950)
Basic and diluted net loss per share	(0.01)	(0.04)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	500,010,114	254,940,675

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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Source: Can-Fite BioPharma Ltd.