August 25, 2022

Can-Fite Reports Second Quarter 2022 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, 2022.

Corporate and Clinical Development Highlights Include:

Strong Balance Sheet - On June 30, 2022, Can-Fite had approximately $12.72 million in cash, cash equivalents, and short-term deposits.

Namodenoson Approved for Compassionate Use in Romania, Pivotal Phase III Liver Cancer Study Open for Enrollment – In August, Can-Fite announced 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 Romanian patient who was enrolled in Can-Fite's prior Phase IIb liver cancer study, and the patient will now continue treatment under the compassionate use program. Can-Fite's pivotal Phase III liver cancer study for Namodenoson is open for enrollment of approximately 450 patients diagnosed with hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to other approved therapies.

Phase III COMFORT™ Trial for Psoriasis Meets Primary Endpoint –Topline results were announced during the second quarter, and further data are expected in the coming weeks. Piclidenoson, Can-Fite's lead drug candidate, successfully met its primary endpoint in the Phase III COMFORT trial in more than 400 adults with moderate to severe plaque psoriasis. At week 16, patients receiving Piclidenoson 3mg demonstrated statistically significant improvement when compared with placebo, as measured by the Psoriasis Area and Severity Index (PASI) 75 response (representing a 75% reduction in psoriasis severity): Piclidenoson 3mg: 9.7% vs. placebo: 2.6% ($P< 0.04$). A linear increase in the response of patients to Piclidenoson was achieved along the study period, on week 48 reaching a PASI 50 response (50% reduction in psoriasis severity) in 90% of patients, a PASI 90 response (90% reduction in psoriasis severity) in 10% of patients, and Psoriasis Disability Index (PDI) improvement in 60% of patients.

Company to Submit FDA & EMA Registration Plans for Piclidenoson for the Treatment Psoriasis – Following the successful COMFORT study, Can-Fite is planning to submit its marketing registration plans to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for Piclidenoson in the treatment of moderate to severe psoriasis. The pivotal Phase III study's protocol is being developed in conjunction with Dr. Kim Papp, a Key Opinion Leader in dermatology and an investigator in the COMFORT study. Current chemistry, manufacturing, and controls (CMC), nonclinical data, and human

pharmacokinetic data will be submitted to the FDA and EMA along with the pivotal Phase III protocol and other supporting clinical pharmacology plans.

Data show Piclidenoson's Superior Safety Profile and Higher Patient Compliance Compared to Otezla® - In July, Can-Fite announced that further analysis of the Phase III COMFORT data point toward a better safety profile for Piclidenoson as compared to Otezla, which induced gastrointestinal adverse events in 6% of patients compared with 1% in patients treated with placebo or Piclidenoson. Discontinuation of treatment amongst patients treated with Otezla was significantly higher compared to that of the Piclidenoson treated patients.

Piclidenoson Demonstrates Higher Efficacy in Patients with More Severe Disease – Also announced in July a sub-analysis of the efficacy data that divided patients into those who had PASI>25 (more severe psoriasis) and PASI<25 (less severe) at baseline revealed that patients who started with higher PASI values at entry benefitted more from treatment with Piclidenoson as compared to placebo.

NASH Patent Granted in Israel, Phase IIb Study is Ongoing – Patient enrollment is ongoing in Can-Fite's Phase IIb study evaluating Namodenoson in 140 subjects with biopsy-confirmed NASH. Can-Fite was granted a patent for NASH titled "An A3 Adenosine Receptor Ligand For Use In Treating Ectopic Fat Accumulation" in Israel, adding to the approximately 40 other countries in which the same patent has been issued.

Piclidenoson to Enter Clinical Trial for Osteoarthritis in Dogs -Through a development and commercialization agreement signed with Vetbiolix, a France based veterinary biotech company in June of 2021, Piclidenoson is set to enter a clinical trial for the treatment of osteoarthritis in dogs. This follows a successfully completed safety study in dogs exploring dose-range safety and pharmacokinetics. Piclidenoson was well tolerated, with the pharmacokinetic data proportional to dose. Vetbiolix is financially responsible for the clinical studies. The canine osteoarthritis market is projected to reach $3 billion by 2028.

"Positive data from our Phase III COMFORT study further supports our belief that Piclidenoson's excellent safety profile, combined with its efficacy as compared to placebo, position it very favorably in the market for psoriasis patients who seek an oral drug that can be used long-term," stated Can-Fite CEO Dr. Pnina Fishman. "As we prepare for a Phase III registration trial for Piclidenoson in psoriasis, we are concurrently advancing our portfolio in several other indications with an aim toward monetizing our significant progress through distribution and collaboration agreements."

Financial Results

Revenues for the six months ended June 30, 2022 were $0.40 million, an increase of $0.01 million, or 2.7%, compared to $0.39 million for the six months ended June 30, 2021. The increase considered to be not material.

Research and development expenses for the six months ended June 30, 2022 were $3.27 million, a decrease of $0.54 million, or 14.2%, compared to $3.81 million for the six months ended June 30, 2021. Research and development expenses for the six months ended June 30, 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 lower costs incurred in 2022 associated with the two studies for Namodenoson and due to the wrap up of the Phase III study of Piclidenoson for the treatment of psoriasis in 2022.

General and administrative expenses for the six months ended June 30, 2022 were $1.57 million a decrease of $0.32 million, or 16.9%, compared to $1.89 million for the six months ended June 30, 2021. The decrease is primarily due to the decrease in professional services and public and investor relations expenses. We expect that general and administrative expenses will remain at the same level through 2022.

Financial expenses, net for the six months ended June 30, 2022 were $0.18 million compared to finance income, net of $0.20 million for the six months ended June 30, 2021. The decrease in financial income, net was mainly due to revaluation of the Company's short-term investment which in 2021 was recorded as income and in 2022 was recorded as expense.

Net loss for the six months ended June 30, 2022 was $4.62 million compared with a net loss of $5.09 million for the six months ended June 30, 2021. The decrease in net loss for the six months ended June 30, 2022 was primarily attributable to a decrease in research and development expenses and a decrease in general and administrative expenses.

As of June 30, 2022, Can-Fite had cash and cash equivalents and short term deposits of $12.72 million as compared to $18.90 million at December 31, 2021. The decrease in cash during the six months ended June 30, 2022 is due to the ongoing operations of the Company.

The Company's consolidated financial results for the six months ended June 30, 2022 are presented in accordance with US GAAP Reporting Standards.

CONSOLIDATED BALANCE SHEETS

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

	June 30, 2022	December 31, 2021
	Unaudited	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,712	$ 4,390
Short term deposit	11,015	14,512
Prepaid expenses and other current assets	1,823	929
Short-term investment	39	237
Total current assets	14,589	20,068

NON-CURRENT ASSETS:		
Operating lease right of use assets	111	138
Property, plant and equipment, net	46	47
Total non-current assets	157	185
Total assets	$ 14,746	$ 20,253

CONSOLIDATED BALANCE SHEETS

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

	June 30, 2022	December 31, 2021
	Unaudited	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 824	$ 954
Current maturity of operating lease liability	47	53
Deferred revenues	818	818
Other accounts payable	464	905
Total current liabilities	2,153	2,730
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	40	71
Deferred revenues	2,661	3,070
Total non-current liabilities	2,701	3,141
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		

Ordinary shares of NIS 0.25 par value - Authorized: 5,000,000,000 shares at June 30, 2022 and December 31, 2021; Issued and outstanding: 815,746,293 shares as of June 30, 2022 and December 31, 2021	60,654	60,654
Additional paid-in capital	93,410	93,275
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(145,299)	(140,674)
Total shareholders' equity	9,892	14,382
Total liabilities and shareholders' equity	$ 14,746	$ 20,253

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Six months ended June 30,	
	2022	**2021**
Revenues	$ 409	$ 398
Research and development expenses	(3,273)	(3,810)
General and administrative expenses	(1,576)	(1,892)
Operating loss	(4,440)	(5,304)
Total financial income (expense), net	(185)	207
Net loss	$ (4,625)	$ (5,097)
Basic and diluted net loss per share	$ (0.00)	$ (0.01)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	815,746,293	500,010,114

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 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 24, 2022 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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