August 31, 2023

Can-Fite Reports Second Quarter 2023 Financial Results & Progress in Two Pivotal Phase III Clinical Studies

PETACH TIKVA, Israel--(BUSINESS WIRE)-- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncology, inflammatory and liver diseases, today announced financial results for the six months ended June 30, 2023.

Clinical Progress

Pivotal Phase III Advanced Liver Cancer Study—Can-Fite's pivotal Phase III liver cancer study, Liveration, which continues enrollment is designed to assess Namodenoson in the treatment of patients with advanced hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to one or two other lines of therapy. The primary endpoint is overall survival. An interim analysis will be conducted by an Independent Data Monitoring Committee (IDMC) after 50% of the planned 450 patients are enrolled and treated.

Breakthrough Abstract Award–Can-Fite was recently granted a prestigious Breakthrough Abstract Award by the American Society of Clinical Oncology (ASCO) Conquer Cancer Foundation for the development of a novel approach to treat advanced liver cancer with the A3 adenosine receptor agonist, Namodenoson.

Exploratory Phase II Pancreatic Cancer Study—Can-Fite is preparing an open-label Phase II exploratory trial to assess the safety and efficacy of Namodenoson in the treatment of patients with pancreatic cancer who have received at least one previous systemic therapy. In pre-clinical studies, Namodenoson demonstrated a robust anti-growth effect against pancreatic carcinoma, reaching 90% growth inhibition. The mechanism of action entails de-regulation of the Wnt signal transduction pathway, a key modulator of pancreatic carcinoma cell growth.

ASCO Recognition—Can-Fite's pancreatic cancer program received recognition from ASCO when its study titled "Effects of Namodenoson on Pancreatic Carcinoma: Preclinical Evidence" was published in the *Journal of Clinical Oncology* supplement of the 2023 ASCO Annual Meeting Proceedings.

Preparatory Work for Pivotal Phase III Psoriasis Study; Can Fite Received Green Light from FDA and EMA— Following positive responses from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for its registration plan and pivotal Phase III study protocol for Piclidenoson in the treatment of moderate to severe psoriasis, the Company is preparing for study initiation. The FDA requested two Phase III studies and also encouraged the Company to enroll adolescent patients due to Piclidenoson's strong safety profile demonstrated over its development history and prior clinical studies. Can-Fite has submitted to the FDA a pediatric plan to allow the registration

of Piclidenoson for the treatment of adolescents. Inclusion of adolescents for the psoriasis Indication is expected to broaden the market.

Development for Treatment of Lowe Syndrome, a Rare Genetic Disease—Researchers at the University of Naples Federico II and The Telethon Institute of Genetics and Medicine (TIGEM) in Italy found Piclidenoson to be effective in pre-clinical studies for the treatment of Lowe Syndrome. Can-Fite and Fondazione Telethon signed an agreement outlining their collaboration for the development of Piclidenoson for the treatment Lowe Syndrome, a rare genetic disease with no treatment available, and an estimated $100 million treatment market in the U.S. alone.

“With two ongoing studies and two more about to commence in large treatment markets with unmet needs, we continue to advance our late-stage development pipeline to bring our potentially game-changing drugs to market,” stated Can-Fite CEO & CFO Motti Farbstein.

Dr. Pnina Fishman, Can-Fite’s CSO and Executive Chairman added, “We are particularly excited about our entry into the rare genetic disease field with the discovery of Piclidenoson’s efficacy in Lowe Syndrome in pre-clinical studies. Given Piclidenoson’s very favorable safety profile, we believe it will be a good candidate for directly entering advanced stage trials in children and adolescents living with Lowe Syndrome. Rare genetic diseases can have a more direct rapid path to regulatory approval with smaller trial sizes due to the pressing need in a small, unserved patient population. “

Financial Results

Revenues for the six months ended June 30, 2023 were $0.39 million compared to revenues of $0.41 million during the six months ended June 30, 2022. Revenues for the six months ended June 30, 2023 and June 30, 2022 comprised of recognition of a portion of advance payments received under distribution agreements with Gebro, CKD, Cipher and Ewopharma.

Research and development expenses for the six months ended June 30, 2023 were $3.41 million compared with $3.27 million for the same period in 2022. Research and development expenses for the first half of 2023 comprised primarily of expenses associated with the completion of the Phase 3 study of Piclidenoson for the treatment of psoriasis and two ongoing studies for Namodenoson, a Phase 3 study in the treatment of advanced liver cancer and a Phase 2b study for SLD. The increase is primarily due to an increase in expenses associated with Namodenoson.

General and administrative expenses were $1.47 million for the six months ended June 30, 2023 compared to $1.57 million for the same period in 2022. The decrease is primarily due to the decrease in public and investor relations expenses and in directors and officer’s insurance policy premium. We expect that general and administrative expenses will remain at the same level through 2023.

Financial income, net for the six months ended June 30, 2023 was $0.27 million compared to financial expense, net of $0.18 million for the same period in 2022. The decrease in financial expense, net was mainly due to revaluation of our short-term investment and increase in interest income from deposits in 2023.

Net loss for the six months ended June 30, 2023 was $4.22 million compared with a net loss

of $4.62 million for the six months ended June 30, 2022. The decrease in net loss for the six months ended June 30, 2023 was primarily attributable to the increase in finance income, net.

As of June 30, 2023, Can-Fite had cash and cash equivalents and short term deposits of $9.60 million as compared to $7.98 million at December 31, 2022. The decrease in cash during the six months ended June 30, 2023 is due to the ongoing operations of the Company.

The Company's consolidated financial results for the six months ended June 30, 2023 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, 2023 Unaudited	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,458	$ 2,978
Short term deposits	6,147	5,001
Prepaid expenses and other current assets	1,293	1,170
Short-term investment	11	8
Total current assets	10,909	9,157
NON-CURRENT ASSETS:		
Operating lease right of use assets	87	84
Property, plant and equipment, net	36	42
Total non-current assets	123	126
Total assets	$ 11,032	$ 9,283

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

	June 30, 2023	December 31, 2022

	Unaudited	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 810	$ 896
Current maturity of operating lease liability	44	48
Deferred revenues	783	783
Other accounts payable	596	775
Total current liabilities	2,233	2,502
NON-CURRENT LIABILITIES:		
Long-term operating lease liability	22	14
Deferred revenues	1,903	2,295
Total long-term liabilities	1,925	2,309
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no-par value - Authorized: 5,000,000,000 shares at June 30, 2023 and December 31, 2022; Issued and outstanding: 1,224,837,393 and 815,746,293 shares as of June 30, 2023 and December 31, 2022	-	-
Additional paid-in capital	160,814	154,192
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(155,067)	(150,847)
Total equity	6,874	4,472
Total liabilities and shareholders' equity	$ 11,032	$ 9,283

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S dollars in thousands (except for share and per share data)

	Six months ended June 30,	
	2023	2022
	Unaudited	

Revenues	$ 392	$ 409
Research and development expenses	(3,417)	(3,273)
General and administrative expenses	(1,471)	(1,576)
Operating loss	(4,496)	(4,440)
Total financial income (expense), net	276	(185)
Net loss	(4,220)	(4,625)
Basic and diluted net loss per share	(0.00)	(0.00)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	1,202,110,110	815,746,293

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF) 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 recently reported topline results in a Phase III trial for psoriasis and is expected to commence a pivotal Phase III. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase IIb trial for the treatment of steatotic liver disease (SLD), a Phase III pivotal trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase IIa study in pancreatic 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 1,600 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 30, 2023 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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