November 30, 2023

Can-Fite Reports Third Quarter 2023 Financial Results and Clinical Update

Advanced liver cancer patient in prior Phase II study remains cancer-free 6.9 years after starting treatment with Namodenoson

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 oncological and inflammatory diseases, today announced financial results for the nine months ended September 30, 2023.

Clinical & Development Milestones Achieved

Namodenoson Drug Candidate:

Complete Response and 6.9 Year Survival Reported in Patient with Advanced Liver Cancer Treated with Namodenoson

A patient who had participated in Can-Fite's prior Phase II liver cancer study who continues to receive treatment with Namodenoson under a compassionate use program now has overall survival of 6.9 years with the disappearance of ascites, normal liver function, and good quality of life, defined as a complete response. Enrollment is ongoing in Can-Fite's pivotal Phase III study of Namodenoson in the treatment of advanced liver cancer. During the third quarter, the American Society of Clinical Oncology (ASCO) selected Can-Fite for the prestigious Breakthrough Abstract Award from Conquer Cancer® for its abstract titled "A novel approach for the treatment of advanced hepatocellular carcinoma (HCC)".

Pancreatic Carcinoma Phase IIa Study with Namodenoson is Underway

Namodenoson inhibited the growth of pancreatic carcinoma in a pre-clinical study through a mechanism that entails the Ras pathway. The Company continues to receive awards and recognition from leading cancer associations, and articles summarizing Namodenoson's robust anti-cancer effect in pancreatic carcinoma have been published. The American Association of Cancer Research (AACR) accepted Can-Fite's study titled "Namodenoson Inhibits the Growth of Pancreatic Carcinoma via De-regulation of the Wnt/β-catenin Signaling Pathway" for a poster presentation at the AACR Special Conference on Pancreatic Cancer. *Biomolecules*, a peer-reviewed scientific journal focused on the function and mechanism of bioactive molecules, published an article titled "Namodenoson Inhibits the Growth of Pancreatic Carcinoma via Deregulation of the Wnt/β-catenin, NF-κB, and RAS Signaling Pathways".

Piclidenoson Drug Candidate:

Entered Rare Genetic Disease Market with Treatment for Lowe Syndrome

In preclinical studies, Piclidenoson has been found to be effective in Lowe Syndrome, a rare

genetic disease with no treatment available, and an estimated $100 million treatment market in the U.S. alone. Lowe Syndrome usually develops in the first year of life, causing brain abnormalities associated with intellectual disabilities and a life span shortened to less than 40 years. The discovery of Piclidenoson's efficacy in Lowe Syndrome was made by researchers at the University of Naples Federico II and The Telethon Institute of Genetics and Medicine in Italy after testing thousands of compounds in search of a treatment. Can-Fite and Fondazione Telethon signed an agreement outlining their collaboration for the development of Piclidenoson for the treatment of Lowe Syndrome. As a rare genetic disease in dire need of a treatment, Lowe Syndrome may qualify for an accelerated approval path, and Can-Fite plans to move into an advanced stage clinical study in this indication.

Harnessing Artificial Intelligence (AI) to Identify and Accelerate New Oncology Programs:

Through an agreement with Collaborations Pharmaceuticals, Can-Fite is utilizing AI and machine learning (ML) to develop and bring to market next-generation A3 adenosine receptor (A3AR) oncology drugs at a significantly reduced development time and cost. New molecules will be designed with high affinity and selectivity to A3AR, the target of Can-Fite's platform technology.

"In addition to the several major value-driving milestones achieved during the third quarter, we continue to enroll and treat patients in our pivotal Phase III liver cancer study and Phase IIb study for NASH. Our pivotal Phase III study in psoriasis is expected to commence soon while we also prepare for a Phase IIa study in pancreatic cancer," stated Motti Farbstein, Can-Fite's CEO and CFO. "We believe our advanced stage pipeline with multiple indications positions Can-Fite well for partnerships and for achieving regulatory and market success based on our robust portfolio."

Financial Results

Revenues for the nine months ended September 30, 2023 were $0.59 million compared to revenues of $0.61 million for the same period in 2022. Revenues for the nine months ended September 30, 2023 and September 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 nine months ended September 30, 2023 were $4.71 million compared with $5.30 million for the same period in 2022. Research and development expenses for the nine months ended September 30, 2023 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.

General and administrative expenses were $2.23 million for the nine months ended September 30, 2023 compared to $2.31 million for the same period in 2022. The decrease is primarily due to the decrease 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 nine months ended September 30, 2023 was $0.38 million compared to financial expense, net of $0.14 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 nine months ended September 30, 2023 was $5.98 million compared with a net loss of $7.15 million for the same period in 2022. The decrease in net loss for the nine months ended September 30, 2023 was primarily attributable to the decrease in research and development expenses and in general and administrative expenses.

As of September 30, 2023, Can-Fite had cash and cash equivalents and short term deposits of $7.94 million as compared to $7.98 million at December 31, 2022. The decrease in cash during the nine months ended nine 30, 2023 is due to the ongoing operations of the Company which was offset by the Company's fundraise during January 2023. During November 2023, Can-Fite raised approximately $3 million from the exercise of certain warrants.

The Company's consolidated financial results for the nine months ended September 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)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,383	$ 2,978
Short term deposits	4,556	5,001
Prepaid expenses and other current assets	1,122	1,170
Short-term investment	3	8
Total current assets	9,064	9,157
NON-CURRENT ASSETS:		
Operating lease right of use assets	72	84
Property, plant and equipment, net	33	42
Total non-current assets	105	126
Total assets	$ 9,169	$ 9,283

CONSOLIDATED BALANCE SHEETS

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

	September 30, 2023	December 31, 2022
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 647	$ 896
Current maturity of operating lease liability	34	48
Deferred revenues	783	783
Other accounts payable	746	775
Total current liabilities	2,210	2,502
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	17	14
Deferred revenues	1,707	2,295
Total long-term liabilities	1,724	2,309
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no-par value - Authorized: 5,000,000,000 shares at September 30, 2023 and December 31, 2022; Issued and outstanding: 1,224,837,393 and 815,746,293 shares as of September 30, 2023 and December 31, 2022	-	-
Additional paid-in capital	160,937	154,192
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(156,829)	(150,847)
Total shareholders' equity	5,235	4,472
Total liabilities and shareholders' equity	$ 9,169	$ 9,283

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Nine months ended September 30,	
	2023	2022
Revenues	$ 588	$ 613
Research and development expenses	(4,716)	(5,309)
General and administrative expenses	(2,233)	(2,317)
Operating loss	(6,361)	(7,013)
Total financial income (expense), net	379	(141)
Net loss	(5,982)	(7,154)
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	1,209,797,279	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.canfite.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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