June 1, 2023

Can-Fite Reports First Quarter 2023 Financial Results & Provides Clinical Update

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 three months ended March 31, 2023.

Clinical and Corporate Development Highlights Include:

NAMODENOSON

Oncology

Pivotal Phase 3 Liver Cancer Study—Can-Fite's ongoing pivotal Phase 3 liver cancer study 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 1 or 2 other lines of therapy. The primary endpoint is overall survival. An interim analysis will be performed.

During the first quarter, a study titled "Targeting the A3 adenosine receptor to treat hepatocellular carcinoma: anti-cancer and hepatoprotective effects" was published in the peer-reviewed journal *Purinergic Signalling.*

Phase 2a Pancreatic Cancer Study—Can-Fite is preparing for an open-label Phase 2 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. Safety and efficacy endpoints including objective response, progression-free survival, duration of response, disease control, and overall survival will be monitored. The study will be conducted by Dr. Salomon Stemmer, an oncology key opinion leader and Professor at the Institute of Oncology, Rabin Medical Center, Israel. In pre-clinical studies, Namodenoson had a significant anti-cancer effect in pancreatic carcinoma as a monotherapy and an additive effect when combined with gemcitabine, the standard-of-care chemotherapy for pancreatic cancer. The mechanism of action entails de-regulation of the Wnt signal transduction pathway, a key modulator of pancreatic carcinoma cell growth.

Can-Fite filed a patent application that covers the use of Namodenoson for the treatment of pancreatic cancer. Moreover, 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.

Pancreatic cancer is an unmet medical need. According to the American Society of Clinical Oncology (ASCO), in 2020, an estimated 496,000 people were diagnosed with pancreatic

cancer globally and an estimated 466,000 died from the disease. The 5-year survival rate for people with pancreatic cancer in the U.S. is 11%. Acumen Research estimates the global pancreatic cancer therapeutics market was valued at approximately $3.6 billion in 2021 and is projected to grow to approximately $6.6 billion by 2030.

Liver Diseases

Phase 2b NASH Study—A Phase 2b NASH study is currently ongoing to evaluate Namodenoson's efficacy as compared to placebo, determined by a histological endpoint. Namodenoson met its primary endpoint of reducing liver fat, inhibiting fibrosis, and demonstrating an anti-inflammatory effect in a prior Phase 2a NASH study.

Compassionate Use in Patients with Decompensated Liver Cirrhosis—Based on data showing that Namodenoson has liver protective effects, Namodenoson is now given to patients with decompensated cirrhosis, an advanced form of cirrhosis associated with liver failure for which there are no therapeutic options other than liver transplantation. Patients will be treated with Namodenoson at the Soroka Medical Center in Israel under compassionate use.

Decompensated cirrhosis is an acute deterioration in liver function in patients with cirrhosis, characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome, or variceal hemorrhage. This is an unmet medical need and there is no therapeutic approach that has shown efficacy in slowing disease progression. An estimated 10.6 million people globally had decompensated cirrhosis in 2017, with few treatment options available aside from liver transplants if the decompensated cirrhosis has reached an advanced stage. The treatment of liver cirrhosis in the U.S. is estimated to become an approximately $15 billion market by 2030.

PICLIDENOSON

Green Light from EMA for a Pivotal Phase 3 Psoriasis Study—The European Medicines Agency (EMA) gave Can-Fite a positive opinion on its registration plan for a pivotal Phase 3 clinical trial for Piclidenoson in the treatment of moderate to severe psoriasis. The pivotal study and the safety of the 3 mg twice daily dose of Piclidenoson are accepted by the agency.

Can-Fite has submitted a comparable data package to the U.S. Food and Drug Administration (FDA) and expects a similar response.

Corporate Developments

New Management Structure as Advanced Stage Pipeline Moves Toward Commercialization—Effective June 30, 2023, executive changes go into effect to support the Company's continued success. Motti Farbstein will lead Can-Fite as Chief Executive Officer and continue to serve as its Chief Financial Officer. Dr. Pnina Fishman, Can-Fite's Scientific Founder, will move from her position as CEO to become Executive Chairman of the Board as well as continuing to serve as Chief Scientific Officer.

Raised $7.5 Million—In January 2023, Can-Fite raised $7.5 million through a concurrent registered direct offering and private placement. The Company's cash and equivalents on

March 31, 2023 was $12.4 million and is expected to cover all clinical development programs and general and administrative expenses for more than a year from the date of this press release.

“During 2023 we plan to increase our efforts towards establishing additional distribution deals and partnerships. We continue to make progress with our two main indications, liver cancer and psoriasis, as we open additional avenues with niche indications based on evidence of the efficacy and safety of our drugs,” stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Revenues for the three months ended March 31, 2023 were $0.19 million, a decrease of $0.01 million, or 4.40%, compared to $0.20 million for the three months ended March 31, 2022. The decrease in revenues is considered to be immaterial.

Research and development expenses for the three months ended March 31, 2023 were $2.06 million, an increase of $0.24 million, or 13.17%, compared to $1.82 million for the three months ended March 31, 2022. Research and development expenses for the first quarter 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 NASH. The increase is primarily due to an increase in expenses associated with Namodenoson.

General and administrative expenses for the three months ended March 31, 2023 were $0.84 million an increase of $0.09 million, or 12.33%, compared to $0.75 million for the three months ended March 31, 2022. The increase is primarily due to the increase in travel expenses and increase in accrued bonuses to the Company’s employees. We expect that general and administrative expenses will remain at the same level through 2023.

Financial income, net for the three months ended March 31, 2023 was $0.16 million compared to finance expense, net of $0.06 million for the three months ended March 31, 2022. The increase in financial income, net was mainly due to exchange rate differences which in 2023 was recorded as income and in 2022 was recorded as expense and revaluation of our short-term investment which in 2023 was recorded as income and in 2022 was recorded as expense.

Net loss for the three months ended March 31, 2023 was $2.55 million compared with a net loss of $2.43 million for the three months ended March 31, 2022. The increase in net loss for the three months ended March 31, 2023 was primarily attributable to an increase in research and development expenses which was partly offset by an increase in finance income, net.

As of March 31, 2023, Can-Fite had cash and cash equivalents and short term deposits of $12.4 million as compared to $7.98 million at December 31, 2022. The increase in cash during the three months ended March 31, 2023 is due to the issuance of share capital and warrants which was offset by ongoing operations of the Company.

The Company's consolidated financial results for the three months ended March 31, 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)

	March 31, 2023 Unaudited	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,264	$ 2,978
Short term deposit	11,135	5,001
Prepaid expenses and other current assets	962	1,170
Short-term investment	18	8
Total current assets	13,379	9,157
NON-CURRENT ASSETS:		
Operating lease right of use assets	70	84
Property, plant and equipment, net	40	42
Total non-current assets	110	126
Total assets	$ 13,489	$ 9,283

CONSOLIDATED BALANCE SHEETS

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

	March 31, 2023 Unaudited	December 31, 2022
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 963	$ 896

Current maturity of operating lease liability	42	48
Deferred revenues	783	783
Other accounts payable	1,103	775
Total current liabilities	2,891	2,502
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	6	14
Deferred revenues	2,099	2,295
Total long-term liabilities	2,105	2,309
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no-par value - Authorized: 5,000,000,000 shares at March 31, 2023 and December 31, 2022; Issued and outstanding: 1,224,837,393 and 815,746,293 shares as of March 31, 2023 and December 31, 2022	-	-
Additional paid-in capital	160,763	154,192
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(153,397)	(150,847)
Total equity	8,493	4,472
Total liabilities and shareholders' equity	$ 13,489	$ 2,983

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Three months ended March 31,	
	2023	**2022**
	Unaudited	
Revenues	$ 196	$ 205
Research and development expenses	(2,061)	(1,821)
General and administrative expenses	(847)	(754)
Operating loss	(2,712)	(2,370)

Total financial income (expense), net	162	(64)
Net loss attributed to ordinary shareholders	(2,550)	(2,434)
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	1,178,872,101	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 anti-inflammatory drug Piclidenoson reported topline results in a Phase 3 trial for psoriasis and is expected to commence a pivotal Phase 3. Can-Fite's cancer and liver drug, Namodenoson, is being evaluated in a Phase 2b trial for the treatment of non-alcoholic steatohepatitis (NASH), enrollment is expected to commence in a Phase 3 trial for hepatocellular carcinoma (HCC), and the Company is planning a Phase 2a 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 1,500 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 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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