November 25, 2022

Can-Fite Reports Third 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 September 30, 2022.

Corporate and Clinical Development Highlights Include:

Complete Clearance of Cancer in a Patient Treated with Namodenoson was Presented at the AASLD Liver Meeting® – A poster titled "Complete Response Induced by Namodenoson, an A3 Adenosine Receptor Agonist, in a Patient with Advanced Hepatocellular Carcinoma" was presented at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® in November in Washington, D.C. The findings were published in the October 2022 supplement of HEPATOLOGY, a premier peer-reviewed journal in the field of liver disease. The poster detailed the patient, a 61-year-old woman with hepatocellular carcinoma (HCC), the most common form of liver cancer, and moderate hepatic dysfunction Child-Pugh B (CPB7), who participated in Can-Fite's prior Phase II study. The patient was in the Namodenoson arm of the Phase II study and continued treatment with Namodenoson for 5 years under an open label extension program until the approval of a compassionate use program in Romania in August.

Namodenoson Approved for Compassionate Use in Romania to Treat Liver Cancer; Phase III Pivotal Global Study Open for Enrolment – Romania became the second country to approve Namodenoson for compassionate use in patients with advanced liver cancer. Can-Fite's global pivotal Phase III liver cancer study for Namodenoson is open for enrollment of approximately 450 patients diagnosed with HCC and underlying CPB7 who have not responded to other approved therapies.

New Psoriasis Data from Phase III COMFORT™ Trial Show Superior Safety & Improved Efficacy – The latest findings on Piclidenoson, Can-Fite's lead drug candidate, from its Phase III COMFORT trial were presented in September at the 31st European Academy of Dermatology and Venerology by Dr. Kim A. Papp, MD, a prominent thought leader in the treatment of psoriasis. In addition to the study meeting its primary endpoint of Piclidenoson's superiority over placebo, the latest data showed that Piclidenoson had a significantly better tolerability profile than Otezla, the leading oral psoriasis treatment on the market today. GI-related adverse events were 1% for Piclidenoson vs. 6% for Otezla, nervous system disorders were 0.7% for Piclidenoson vs. 9.9% for Otezla and 3.3% for the placebo. The discontinuation rate was significantly higher for Otezla than for Piclidenoson. In achieving psoriasis disability index (PDI) response at week 32, Piclidenoson was comparable to Otezla. Patients treated with Piclidenoson showed an improving progressive response over time, a critically important finding given psoriasis is a chronic disease that

may require long-term treatment.

Pivotal Phase III Psoriasis Registration Study is Under Preparation for Submission to FDA & EMA – The pivotal Phase III psoriasis 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. Marketing registration plans including chemistry, manufacturing, and controls (CMC), nonclinical data, and human pharmacokinetic data are being prepared for submission 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.

Safety Study of Piclidenoson for Osteoarthritis in Dogs Successfully Concluded, Efficacy Study to Commence - Following a successful safety study in dogs that explored dose-range safety and pharmacokinetics, Piclidenoson is set to enter efficacy studies in the treatment of canine osteoarthritis through a development and commercialization agreement signed with Vetbiolix, a France based veterinary biotech company. Vetbiolix is financially responsible for the clinical studies. The canine osteoarthritis market is projected to reach $3 billion by 2028 and regulatory approval pathways tend to be shorter than those required for humans.

"The latest Phase III findings for Piclidenoson are highly encouraging and inform the potential for a successful psoriasis registration study which will be conducted under both the FDA and EMA. A favorable outcome could mean marketing approval in two of the largest markets in the world," stated Can-Fite CEO Dr. Pnina Fishman. "While we have distribution agreements in place for Piclidenoson and Namodenoson in the treatment of psoriasis and liver cancer in certain European and Asian markets, we maintain full distribution rights for these late-stage assets in the U.S., the largest market in the world. We are strategically evaluating partnerships in the U.S. as we continue to forge ahead on each of our other indications including Namodenoson in NASH and Piclidenoson for canine osteoarthritis."

Financial Results

Revenues for the nine months ended September 30, 2022 were $0.61 million, a decrease of $0.04 million, or 6.1%, compared to $0.65 million for the nine months ended September 30, 2021. The decrease is considered to be not material.

Research and development expenses for the nine months ended September 30, 2022 were $5.31 million, a decrease of $1.44 million, or 21.3%, compared to $6.75 million for the nine months ended September 30, 2021. Research and development expenses for the nine months ended September 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 the wrap up of the Phase III study of Piclidenoson for the treatment of psoriasis in 2022.

General and administrative expenses for the nine months ended September 30, 2022 were $2.31 million a decrease of $0.40 million, or 14.7%, compared to $2.71 million for the nine months ended September 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 nine months ended September 30, 2022 were $0.14 million compared to finance income, net of $0.31 million for the nine months ended September 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 nine months ended September 30, 2022 was $7.15 million compared with a net loss of $8.50 million for the nine months ended September 30, 2021. The decrease in net loss for the nine months ended September 30, 2022 was primarily attributable to a decrease in research and development expenses and a decrease in general and administrative expenses.

As of September 30, 2022, Can-Fite had cash and cash equivalents and short term deposits of $10.79 million as compared to $18.90 million at December 31, 2021. The decrease in cash during the nine months ended September 30, 2022 is due to the ongoing operations of the Company.

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

	September 30, 2022	December 31, 2021
	Unaudited	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,727	$ 4,390
Short term deposit	7,071	14,512
Prepaid expenses and other current assets	1,752	929
Short-term investment	15	237
Total current assets	12,565	20,068
NON-CURRENT ASSETS:		
Operating lease right of use assets	98	138
Property, plant and equipment, net	43	47
Total non-current assets	141	185

Total assets	$ 12,706	$ 20,253

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

	September 30, 2022	December 31, 2021
	Unaudited	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,472	$ 954
Current maturity of operating lease liability	48	53
Deferred revenues	818	818
Other accounts payable	458	905
Total current liabilities	2,796	2,730
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	26	71
Deferred revenues	2,456	3,070
Total non-current liabilities	2,482	3,141
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of NIS 0.25 par value - Authorized: 5,000,000,000 shares at September 30, 2022 and December 31, 2021; Issued and outstanding: 815,746,293 shares as of September 30, 2022 and December 31, 2021	60,654	60,654
Additional paid-in capital	93,475	93,275
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(147,828)	(140,674)
Total shareholders' equity	7,428	14,382

Total liabilities and shareholders' equity	$ 12,706	$ 20,253

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

	Nine months ended September	
	2022	
Revenues	$ 613	$
Research and development expenses	(5,309)	
General and administrative expenses	(2,317)	
Operating loss	(7,013)	
Total financial income (expense), net	(141)	
Net loss	$ (7,154)	$
Basic and diluted net loss per share	$ (0.01)	$
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	815,746,293	51

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 recently reported topline results 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 enrollment is expected to commence in 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20221125005018/en/

Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

Source: Can-Fite BioPharma Ltd.