April 14, 2025

Can-Fite Reports 2024 Financial Results and Clinical Update

Cancer-Free Survival of 8 Years in Liver Cancer Patient Treated with Namodenoson in Prior Phase II Study

RAMAT GAN, Israel, April 14, 2025 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF), a biotechnology company developing a pipeline of proprietary small molecule drugs targeting oncological and inflammatory diseases, today announced financial results and clinical updates for the year ended December 31, 2024.

Clinical & Development Milestones Achieved

Namodenoson Drug Candidate:

Liver Cancer - A patient, who initially had an overall survival time of 8 years, currently treated with Namodenoson in a compassionate use program in the former Can-Fite Phase II study has evidenced a complete cure manifested by the disappearance of all metastases, normal liver function and good quality of life. In addition, the Company has found that Namodenoson has protective effects on top of the anti-cancer activity that was presented at the 2025 ASCO Gastrointestinal Cancers Symposium and also published in European Society of Medicine Journal entitled: “The Neuro- Cardio- and Hepato- Protective Effects of Namodenoson are Mediated by Adiponectin”. The article presents compelling preclinical and clinical data demonstrating Namodenoson’s potent anti-ischemic, anti-inflammatory, anti-fibrotic, and anti-toxicity effects across multiple body tissues, including the liver, central nervous system and cardiovascular system. The study highlights Namodenoson’s ability to increase adiponectin levels, a key cytokine known to drive multi-organ protective effects. Importantly, the manuscript underscores Namodenoson’s dual role as both an anti-cancer therapy and a protective agent for normal tissues, setting it apart from conventional chemotherapy and other oncology treatments with significant toxicity.

Pancreatic Cancer - Namodenoson has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the indication of pancreatic cancer, one of the most aggressive malignancies. The designation as an orphan drug will provide, among others, potential for market exclusivity for seven years after approval and several and regulatory advantages (https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions). In addition, the Company initiated a Phase IIa clinical trial in patients with advanced pancreatic adenocarcinoma (NCT06387342). The Phase IIa study is a multicenter open-label trial in patients with advanced pancreatic adenocarcinoma whose disease has progressed on at least first-line therapy. The trial is evaluating the safety, clinical activity and pharmacokinetics (PK) of Namodenoson in this patient population. Recently, the FDA approved compassionate use treatment of a U.S.-based pancreatic cancer patient with its anti-cancer drug Namodenoson.

Anti-Obesity - Namodenoson was granted a patent for its use as an anti-obesity drug by the

U.S. patent office. The patent application (No. 17/309,952) entitled, “An A3 adenosine receptor ligand for use for achieving a fat loss effect”, has been accepted by the U.S. Patent Office, was issued in February 2024 and expires in 2042.

The patent application covers methods of treating obese patients by administering Namodenoson in an oral formulation. In addition, the Company was also granted a patent application (No.2020205042) for the anti-obesity indication by the Australian Patent Office, which expires in 2040.

Piclidenoson Drug Candidate:

Psoriasis – Can-Fite initiated a pivotal phase 3 psoriasis study of its oral drug, Piclidenoson, with the FDA and the European Medicines Agency (EMA). The study will enroll patients with moderate to severe plaque psoriasis. Patient enrolment will be initiated in Europe, with the U.S. and Canada expected to follow.

Lowe Syndrome - Can-Fite recently entered into the clinical development of implementing Piclidenoson into the treatment of the rare genetic disease, Lowe Syndrome. A Phase II design has been completed and preparatory work is being undertaken to initiate the study that will be conducted by Dr. Franchesca Emma from the Division of Nephrology, Bambino Gesù Children's Hospital - IRCCS Rome Italy. The Phase II open-label study will enroll 5 patients that will be treated twice daily with 3 mg Piclidenoson for 12 months. The study’s primary end point will be the efficacy of Piclidenoson in increasing 99mTc-DMSA renal uptake.

Canine Osteoarthritis – Can-Fite partnered with Vetbiolix for the development of Piclidenoson for canine osteoarthritis and successfully concluded a clinical study in dogs with osteoarthritis who were treated orally with Piclidenoson for a period of a few months. The arthritis market for companion animals was estimated by Coherent Market Insights to be $3.8 Billion in 2023 and is expected to grow to $6.3 Billion by 2030. Can-Fite and Vetbiolix model that Piclidenoson has the potential to capture up to 6% of this opportunity, with peak worldwide sales of $445 Million by 2034. Under the agreement, Can-Fite is entitled to receive a 15% royalty on worldwide sales in this indication. This means that Can-Fite’s upfront and royalties on sales upon regulatory approval for veterinary use is projected to be $325 million in the aggregate over the next decade assuming a 2029 launch. In addition, Vetbiolix is initiating an advanced clinical study in dogs with osteoarthritis, utilizing oral daily treatment with Piclidenoson. Expected registration of Piclidenoson for this indication is anticipated to be in 2029.

Financial Results

Revenues for the year ended December 31, 2024 were $0.67 million, a decrease of $0.07 million, or 9.3%, compared to $0.74 million for the year ended December 31, 2023. The decrease in revenues was mainly due to the recognition a lower portion of advance payments received under distribution agreements that the Company previously entered into, offset by a recognition of advance payment received under the license agreement with Vetbiolix.

Research and development expenses for the year ended December 31, 2024 were $5.75 million, a decrease of $0.23 million, or 3.8%, compared to $5.98 million for the year ended

December 31, 2023. Research and development expenses for the year ended December 31, 2024 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 MASH. The decrease is primarily due to a decrease in expenses associated with Piclidenoson.

General and administrative expenses were $3.04 million for the year ended December 31, 2024, an increase of $0.09 million, or 3.1%, compared to $2.95 million for the year ended December 31, 2023. The increase is primarily due to higher public relations expenses. The Company expects that general and administrative expenses will remain at the same level through 2025.

Financial income, net for the year ended December 31, 2024, aggregated $0.25 million, compared to $0.56 million for the year ended December 31, 2023. The decrease in financial income, net was mainly due to a decrease in interest from deposits.

Net loss for the year ended December 31, 2024, was $7.88 million, compared with a net loss of $7.63 million for the same period in 2023. The increase in net loss for the year ended December 31, 2024, is considered immaterial.

As of December 31, 2024, Can-Fite had cash and cash equivalents and short term deposits of $7.88 million as compared to $8.90 million as of December 31, 2023. The decrease in cash during the year ended December 31, 2024 is due to the ongoing operations of the Company.

The Company's consolidated financial results for the year ended December 31, 2024 are presented in accordance with US GAAP Reporting Standards.

More detailed information can be found in the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2024, a copy of which has been filed with the Securities and Exchange Commission (SEC). The Annual Report, which contains the Company’s audited consolidated financial statements, can be accessed on the SEC’s website at http://www.sec.gov/ as well as via the Company’s investor relations website at https://ir.canfite.com. The Company will deliver a hard copy of its Annual Report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Can-Fite Investor Relations at 26 Ben Gurion Street, Ramat Gan, 5257346, Israel or by phone at +972-3-9241114.

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

	December 31,	
	2024	**2023**
ASSETS		
CURRENT ASSETS:		

Cash and cash equivalents	$ 4,825	$ 4,278
Short term deposits	3,057	4,625
Prepaid expenses and other current assets	1,095	986
Short-term investment	5	19
Total current assets	8,982	9,908
NON-CURRENT ASSETS:		
Operating lease right of use assets	111	52
Property, plant and equipment, net	27	29
Total non-current assets	138	81
Total assets	$ 9,120	$ 9,989

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

	December 31,	
	2024	**2023**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 618	$ 427
Current maturity of operating lease liability	53	27
Deferred revenues	405	622
Other accounts payable	976	944
Total current liabilities	2,052	2,020
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	51	13
Deferred revenues	1,581	1,713
Total long-term liabilities	1,632	1,726

CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no-par value - Authorized: 10,000,000 and 5,000,000,000 shares at December 31, 2024 and December 31, 2023; Issued and outstanding: 2,983,181,793 and 1,359,837,393 shares as of December 31, 2024 and December 31, 2023	-	-
Additional paid-in capital	170,670	163,597
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(166,361)	(158,481)
Total shareholders' equity	5,436	6,243
Total liabilities and shareholders' equity	$ 9,120	$ 9,989

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

	Year ended December 31,	
	2023	**2022**
Revenues	$ 674	$ 743
Research and development expenses	(5,757)	(5,983)
General and administrative expenses	(3,047)	(2,955)
Operating loss	(8,130)	(8,195)
Total financial income, net	250	561
Net loss	(7,880)	(7,634)
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	2,175,926,512	1,278,333,912

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 reported topline results in a Phase III trial for psoriasis and commenced a pivotal Phase III trial. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in 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: https://www.canfite.com/.

Forward-Looking Statements

This press release contains 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, including statements regarding projected revenue. 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 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 April 14, 2025 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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