March 28, 2024

Can-Fite Reports 2023 Financial Results and Clinical Update

Ewopharma acquired marketing rights for namodenoson in the treatment of pancreatic carcinoma

RAMAT GAN, 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 and clinical updates for the twelve months ended December 31, 2023.

Recent Clinical & Development Milestones Achieved

Namodenoson Drug Candidate:

1. **Ewopharma recently acquired marketing rights for Namodenoson in the treatment of pancreatic carcinoma**
   This adds up to an out licensing agreement that Can-Fite signed with Switzerland-based Ewopharma in 2021, for exclusive distribution of both Piclidenoson and Namodenoson in Central Eastern European (CEE) countries (Piclidenoson for the treatment of psoriasis and Namodenoson for the treatment of liver cancer and NASH). Under the terms of the distribution agreement, Ewopharma AG paid Can-Fite an upfront payment of US$2.25 million with up to an additional US$40.45 million, payable upon the achievement of regulatory and sales milestones, plus 17.5% royalties on net sales. Recently, Ewopharma AG exercised its right to expand the distribution agreement to include the indication of pancreatic cancer and the transaction terms of the distribution agreement are applicable to such indication.
2. **Can-Fite Broadens its Strong Intellectual Property (IP) for NASH (MASH): Received Patent Allowance in Canada**
   Can-Fite received a Notice of Allowance from the Canadian Intellectual Property Office for its patent application titled “An A3 Adenosine Receptor Ligand For Use In Treating Ectopic Fat Accumulation”. This invention addresses the use of Namodenoson for the reduction of liver fat in patients with NASH a clinical indication that is being developed by Can-Fite. In a successfully concluded Phase IIa study, Namodenoson, one of the Company’s two drugs in advanced clinical development, reduced liver fat content, showed anti-inflammatory effects manifested by a significant decrease in the liver enzymes ALT & AST, and decreased body weight in patients with NASH. A Company-sponsored study for Namodenoson for this indication is currently enrolling patients for a Phase IIb study which will include 140 patients, in whom liver pathology is the primary endpoint. Patent has already been issued in other major markets including the U.S., EU, Japan and China.

Piclidenoson Drug Candidate:

Positive Data from the COMFORT-1 Phase III Psoriasis Study Published in a Top Scientific Journal

The Journal of the European Academy of Dermatology and Venereology (EADV) published an article titled “Efficacy and safety of piclidenoson in plaque psoriasis: Results from a randomized phase 3 clinical trial (COMFORT-1)”. EADV is a top ranked peer reviewed journal (impact factor 9.2) that publishes articles on clinical and basic science topics in dermatology. The article’s first author, Dr. K.A Papp, is an internationally renowned key opinion leader in the psoriasis field and was the engine for some registered drugs on the market for this devastating skin disease. The EADV article presents the safety and efficacy of Piclidenoson in the randomized, placebo- and active-controlled, double-blind Phase III COMFORT-1 trial. As previously reported, the study met its primary endpoint which was the proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI) from baseline (PASI-75) at Week 16 (3 mg BID dose: PASI 75 rate of 9.7% vs. 2.6% for Piclidenoson vs. placebo, p=0.037). Piclidenoson’s efficacy continued to increase throughout the study period in a linear manner with an excellent safety and tolerability profile. Currently, Piclidenoson is being evaluated in COMFORT-2 a pivotal Phase III study that has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

“Our advanced-stage pipeline continues to achieve milestones, with Piclidenoson and Namodenoson both positioned as potentially safe and effective treatments for the oncological diseases liver cancer & pancreatic carcinoma and the inflammatory and metabolic diseases psoriasis and NASH. We anticipate additional clinical progress and new out licensing deals in this year,” stated Can-Fite CEO Motti Farbstein.

Financial Results

Revenues for the year ended December 31, 2023 were $0.74 million, a decrease of $0.07 million, or 8.6%, compared to $0.81 million for the year ended December 31, 2022. The decrease in revenues was mainly due to the recognition a lower portion of advance payments received under the Ewopharma distribution agreement entered in 2021 and a lower portion of advance payments received under distribution agreements from Gebro, Chong Kun Dung Pharmaceuticals, and Cipher Pharmaceuticals.

Research and development expenses for the year ended December 31, 2023 were $5.98 million, a decrease of $1.78 million, or 22.9%, compared to $7.76 million for the year ended December 31, 2022. Research and development expenses for the year ended December 31, 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 decrease is primarily due to a decrease in expenses associated with Piclidenosnon.

General and administrative expenses were $2.95 million for the year ended December 31, 2023 a decrease of $0.19 million, or 6.05%, compared to $3.14 million for the year ended December 31, 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 2024.

Financial income (expense), net for the year ended December 31, 2023 aggregated $0.56 million compared to financial expense, net of $(0.07) for the year ended December 31, 2022. The decrease in financial expense, net was mainly due to increase interest from deposits

and reduction in expenses related to the revaluation of our short-term investment.

Net loss for the year ended December 31, 2023 was $7.63 million compared with a net loss of $10.17 million for the same period in 2022. The decrease in net loss for the year ended December 31, 2023 was primarily attributable to the decrease in research and development expenses and in general and administrative expenses.

As of December 31, 2023, Can-Fite had cash and cash equivalents and short term deposits of $8.90 million as compared to $7.98 million at December 31, 2022. The decrease in cash during the year ended December 31, 2023 is due to the ongoing operations of the Company which was offset by the Company's financing during January 2023 and exercise of certain warrants during November 2023.

The Company's consolidated financial results for the year ended December 31, 2023 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, 2023, 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,	
	2023	**2022**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,278	$ 2,978
Short term deposits	4,625	5,001
Prepaid expenses and other current assets	986	1,170
Short-term investment	19	8
Total current assets	9,908	9,157
NON-CURRENT ASSETS:		
Operating lease right of use assets	52	84

Property, plant and equipment, net	29	42
Total non-current assets	81	126
Total assets	$ 9,989	$ 9,283

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

	December 31,	
	2023	**2022**
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 427	$ 896
Current maturity of operating lease liability	27	48
Deferred revenues	622	783
Other accounts payable	944	775
Total current liabilities	2,020	2,502
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	13	14
Deferred revenues	1,713	2,295
Total long-term liabilities	1,726	2,309
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		

Ordinary shares of no-par value - Authorized: 5,000,000,000 shares at December 31, 2023 and December 31, 2022; Issued and outstanding: 1,359,837,393 and 815,746,293 shares as of December 31, 2023 and December 31, 2022	-	-
Additional paid-in capital	163,597	154,192
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(158,481)	(150,847)
Total shareholders' equity	6,243	4,472
Total liabilities and shareholders' equity	$ 9,989	$ 9,283

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

	Year ended December 31,	
	2023	**2022**
Revenues	$ 743	$ 810
Research and development expenses	(5,983)	(7,763)
General and administrative expenses	(2,955)	(3,143)
Operating loss	(8,195)	(10,096)
Total financial income (expense), net	561	(77)
Net loss	(7,634)	(10,173)
Basic and diluted net loss per share	(0.01)	(0.01)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	1,278,333,912	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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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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Source: Can-Fite BioPharma Ltd.