August 29, 2024

Can-Fite Reports First Half 2024 Financial Results & Progress in Two Pivotal Phase III Clinical Studies

RAMAT GAN, Israel, Aug. 29, 2024 (GLOBE NEWSWIRE) -- 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 H1 2024.

H1 2024 Highlights

1. **Exercise of Warrants for Approximately $5.0 Million in Gross Proceeds –**in August, the Company announced the exercise of certain outstanding warrants to purchase up to an aggregate of 2,857,143 American Depositary Shares (ADSs), having an exercise price of $1.75 per ADS, issued by Can-Fite in January 2023 and November 2023. In consideration for the immediate exercise of the warrants for cash, the Company issued new unregistered warrants to purchase up to 5,714,286 ADSs.
2. **Piclidenoson Drug Candidate -**
   Positive Results from an Osteoarthritis clinical study in dogs were reported by Can-Fite's partner Vetbiolix, who is developing Piclidenoson for veterinary indications. Vetbiolix concluded successfully the study interim analysis and can now exercise an option to enter into a full in license agreement with Can-Fite. Based on the agreement between the two companies, if it exercises the option, Vetbiolix will be obligated to pay Can-Fite upfront and milestone payments, in addition to royalties on sales upon regulatory approval.
3. **Namodenoson Drug Candidate -**
   Liver Cancer – the Company's Phase 3 pivotal study now has 31 recruiting medical centers in Europe, Israel and the US. Namodenoson has Orphan Drug status with both the U.S. Food and Drug Administration (FDA) and European Medicines Agency, as well as Fast Track Status with the FDA. A compassionate use program has also been ongoing in Israel and Romania. In addition, two scientific articles, one describing long-term complete response to Namodenoson in a patient with advanced liver cancer and the other presents Namodenoson as a promising drug candidate to treat advanced liver cancer and MASH, were published.
   Pancreatic Cancer – the Company received approval from the Institutional Review Board (IRB) of Rabin Medical Center, a leading medical institution in Israel, for a Phase IIa study for the treatment of pancreatic cancer. The Company awaits now the approval of the Ministry of Health (MOH). In addition, the Company submitted an application to the U.S. Food and Drug Administration (FDA) for Orphan Drug Designation for Namodenoson in the treatment of pancreatic carcinoma.
   MASH (metabolic dysfunction-associated steatohepatitis) – the FDA granted IND clearance for Namodenoson to treat MASH patients in a Phase IIb study. Currently Can-Fite is enrolling patients for a Phase IIb clinical study in Europe and in Israel and the IND approval by FDA allows for the recruitment of patients in the US.

“With two drugs in advanced clinical studies we continue to enroll patients and push forward towards a positive conclusion of each program. We continue to position our drugs for multi-billion markets with unmet needs,” stated Can-Fite CEO & CFO Motti Farbstein.

Financial Results

Revenues for the six months ended June 30, 2024 were $0.32 million compared to revenues of $0.39 million for the same period in 2023. Revenues for the six months ended June 30, 2024 and June 30, 2023 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 six months ended June 30, 2024 were $2.89 million compared with $3.42 million for the same period in 2023. Research and development expenses for the first half of 2024 comprised primarily of expenses associated with the 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 Piclidenoson.

General and administrative expenses were $1.53 million for the six months ended June 30, 2024 compared to $1.47 million for the same period in 2023. The decrease is primarily due to the decrease in our D&O insurance policy and decrease in bonus expenses to employees and executives. We expect that general and administrative expenses will remain at the same level through 2024.

Financial income, net for the six months ended June 30, 2024 was $0.14 million compared to $0.28 million for the same period in 2023. The decrease in financial income, net was mainly due to lower income on short term deposits.

Net loss for the six months ended June 30, 2024 was $3.95 million compared with a net loss of $4.22 million for the same period in 2023. The decrease in net loss for the six months ended June 30, 2024 was primarily attributable to the decrease in our operating expenses.

As of June 30, 2024, Can-Fite had cash and cash equivalents and short term deposits of $4.72 million as compared to $8.90 million at December 31, 2023. The decrease in cash during the six months ended June 30, 2024 is due to the ongoing operations of the Company. On August 8, 2024, the Company and a certain warrant holder entered into an inducement offer letter agreement, according to which the warrant holder agreed to exercise for cash warrants to purchase 2,857,143 ADSs at an exercise price of $1.75 per ADS. Total gross consideration received was $5 million. In addition, as part of the inducement letter and the exercise of warrants, the Company has issued the investor new warrants exercisable into 5,714,286 ADSs at an exercise price of $2.25 per ADS. Moreover, the Company also issued to its placement agent new warrants exercisable into 200,000 ADSs at an exercise price of $2.1875 per ADS.

The Company’s condensed consolidated financial results for the six months ended June 30, 2024 are presented in accordance with US GAAP Reporting Standards.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2024 Unaudited	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,719	$ 4,278
Short term deposits	-	4,625
Prepaid expenses and other current assets	1,100	986
Short-term investment	9	19
Total current assets	5,828	9,908
NON-CURRENT ASSETS:		
Operating lease right of use assets	62	52
Property, plant and equipment, net	32	29
Total non-current assets	94	81
Total assets	$ 5,922	$ 9,989

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2024 Unaudited	December 31, 2023
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 885	$ 427

Current maturity of operating lease liability	36	27
Deferred revenues	636	622
Other accounts payable	430	944
Total current liabilities	1,987	2,020
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	21	13
Deferred revenues	1,435	1,713
Total long-term liabilities	1,456	1,726
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of no-par value - Authorized: 5,000,000,000 shares at June 30, 2024 and December 31, 2023; Issued and outstanding: 1,671,728,493 and 1,359,837,393 shares as of June 30, 2024 and December 31, 2023, respectively	-	-
Additional paid-in capital	163,790	163,597
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(162,438)	(158,481)
Total shareholders' equity	2,479	6,243
Total liabilities and shareholders' equity	$ 5,922	$ 9,989

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

	Six months ended June 30,	
	2024	**2023**
	Unaudited	
Revenues	$ 316	$ 392
Research and development expenses	(2,885)	(3,417)
General and administrative expenses	(1,525)	(1,471)

Operating loss	(4,094)	(4,496)
Financial income, net	137	276
Comprehensive loss	(3,957)	(4,220)
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	1,821,304,184	1,202,110,110

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 metabolic dysfunction-associated steatohepatitis (MASH), 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 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.

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

Source: Can-Fite BioPharma Ltd.