August 27, 2020

Can-Fite Reports Second Quarter 2020 Financial Results & Provides Clinical Update

- ***Company to host conference call at 4:15 p.m. ET today, August 27, 2020***
- ***Piclidenoson Phase III rheumatoid arthritis and psoriasis interim data expected Q4 2020***
- ***Achieved efficacy and safety endpoints in Phase II NASH trial***
- ***IND filed with FDA for Phase II study of Piclidenoson in treatment of COVID-19***

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 cancer, liver and inflammatory diseases, today announced financial results for the six months ended June 30, 2020.

Clinical Developments and Corporate Highlights for the Second Quarter and Recent Weeks Include:

Piclidenoson Phase III Rheumatoid Arthritis and Psoriasis Interim Data Expected Q4 2020 – Having enrolled over 50% of patients in its two Phase III studies in rheumatoid arthritis and psoriasis, Can-Fite plans to announce interim analysis for both studies in Q4 2020.

Namodenoson Showed Significant Efficacy in Treating Patients with NAFLD/NASH in a Phase II Study – Can-Fite's Phase II NASH study achieved primary and secondary efficacy and safety endpoints in a dose dependent and statistically significant manner. The study evaluated 60 patients with non-alcoholic fatty liver disease (NAFLD) with or without non-alcoholic steatohepatitis (NASH) who were treated in three arms of the study with either 25mg Namodenoson, 12mg Namodenoson, or placebo. Namodenoson induced significant change in primary and secondary study endpoints over the 12 week study, which is a relatively short period of time. A robust anti-Inflammatory effect manifested by significant decrease in the liver enzymes ALT and AST and significant improvement in the positive cytokine adiponectin was recorded. A reduced liver fat content (LFC) and a reduction in % of liver fat volume was found together with a decrease in FIB-4 and FAST, non-invasive tests used as markers to exclude advanced fibrosis. In addition, a decrease in body weight has been observed in the 2 doses of Namodenoson, with a better effect in the higher dose. The 25mg dose of Namodenoson was found to have optimal efficacy while also having a strong safety profile and was well tolerated. 25mg has been selected as the dose to be used in the Company's next NAFLD/NASH study. The NASH market is projected to reach at least $35 billion by 2025. There are currently no other treatment options approved for this growing unmet need.

Namodenoson Patents for the Treatment of NASH & NAFLD in U.S. and Europe– During the second quarter, the U.S. Patent and Trademark Office granted Can-Fite a patent for Namodenoson in the treatment of NASH and NAFLD. This was followed by the European Patent Office's notification to Can-Fite, after the end of the second quarter, of its intent to grant a similar patent. The patents cover the use of the A3 adenosine receptor (A3AR) in reducing ectopic fat accumulation, particularly in fatty liver and specifically addresses reducing fat accumulation and treating conditions associated with fat accumulation such as fatty liver diseases including NASH and NAFLD.

Namodenoson Headed into Pivotal Phase III Liver Cancer Study in Europe and U.S.– Following a successful meeting with the European Medicines Agency (EMA) during the second quarter, and a prior End-of-Phase II Meeting with the U.S. Food and Drug Administration (FDA), Can-Fite completed its protocol for a pivotal Phase III study of Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. The study is designed to support a New Drug Application submission in the U.S. and a Marketing Authorization Application in Europe. Namodenoson is currently being used to treat liver cancer patients in a compassionate use program in Israel.

IND Filed with FDA for Phase II COVID-19 Study of Piclidenoson– Based on pre-IND advice and guidance from the U.S. FDA during the second quarter, Can-Fite developed a clinical trial protocol and filed an Investigational New Drug (IND) application in July for Piclidenoson in the treatment of COVID-19. A 28-day Phase II study will evaluate hospitalized patients with moderate COVID-19 symptoms. The study titled, "Piclidenoson for Treatment of COVID-19 – A Randomized, Double Blind, Placebo-Controlled Trial" will enroll 40 patients who are receiving standard supportive care and will randomly assign them in a 1:1 ratio to the trial arms of Piclidenoson twice daily or placebo. After 28 days of treatment, efficacy will be assessed through standard measures of clinical and respiratory status at day 29, including the proportion of patients alive and free of respiratory failure, as well as the proportion discharged home without need for supplemental oxygen.

Completed Development of Assay to Identify Clinically Active Cannabis Derived Compounds – Can-Fite completed the development of a biological cell-based in vitro assay which can identify clinically active cannabis derived compounds that bind to and activate A3AR, the target of Can-Fite's platform technology. Numerous studies published in peer reviewed scientific journals demonstrate that cannabis derived compounds bind to the Gi protein-coupled A3AR, which is over-expressed in pathological cells and tissues. In addition to using this assay in the development of its own cannabis derived compound-based therapeutics, Can-Fite plans to market the assay on a 'fee for service' basis to researchers and other cannabis companies worldwide.

Cash Infusion of $12.9 Million – During the second quarter of 2020, Can-Fite received $8 million in a registered direct offering and a further $1.5 million through warrant exercises. In addition, during July, the Company received $3.4 million from in a registered direct offering.

"Following Namodenoson's very encouraging Phase II efficacy and safety results in the treatment of NASH and NAFLD, we are now planning our next study in this indication which is in dire need of an effective treatment as the global prevalence of NAFLD is estimated at 25% and NASH is at 3%–5% of the general population. Achieving primary and secondary endpoints in the Phase II patients treated with 25mg of Namodenoson gives us a clear imperative to advance this clinical program," stated Can-Fite CEO Pnina Fishman.

“In the U.S., we anticipate starting a Phase II COVID-19 study of Piclidenoson upon the FDA’s response to our IND filing. As the spread of COVID-19 infections appears to be difficult to contain, it is more important than ever to rapidly develop and make available effective treatments in parallel with the massive efforts that are going into vaccine development. Looking ahead to the balance of 2020, Can-Fite has several upcoming milestones including interim results from our Phase III studies in rheumatoid arthritis and psoriasis,” Dr. Fishman added.

“The COVID-19 outbreak has had a limited impact on our operations to date. Our ongoing clinical trials and clinical trial preparation work continue to remain on track. We have implemented remote working and workplace protocols for our employees in accordance with Israel Health Ministry guidelines and we continue to closely evaluate the pandemic as it unfolds,” Dr. Fishman concluded.

Financial Results

Revenues for the six months ended June 30, 2020 were $0.40 million compared to revenues of $0.68 million during the six months ended June 30, 2019. The decrease in revenues was mainly due to the recognition of 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 six months ended June 30, 2020 were $7.05 million compared with $3.96 million for the same period in 2019. Research and development expenses for the six months ended June 30, 2020 comprised primarily of expenses associated with the Phase II studies for Namodenoson in the treatment of NASH and HCC, as well as expenses for ongoing Phase III studies of Piclidenoson in the treatment of rheumatoid arthritis and psoriasis. The increase is primarily due to increased costs associated with the accelerating rate of absorption of patients for the Phase III clinical trial of Piclidenoson for the treatment of rheumatoid arthritis and for psoriasis.

General and administrative expenses were $1.45 million for the six months ended June 30, 2020 compared to $1.33 million for the same period in 2019. The increase is primarily due to an increase in salaries and related benefits and insurance expenses which was partly offset by a decrease in travel expenses and professional services.

Financial expenses, net for the six months ended June 30, 2020 was $0.12 million compared to financial expenses, net of $0.28 million for the same period in 2019. The decrease in financial expenses, net is primarily due to a decrease in exchange rate expenses.

Can-Fite's net loss for the six months ended June 30, 2020 was $8.23 million compared with a net loss of $4.89 million for the same period in 2019. As of June 30, 2020, Can-Fite had cash and cash equivalents of $9.05 million as compared to $2.69 million at December 31, 2019. The increase in cash during the six months ended June 30, 2020 is due to an aggregate of $17.9 million received through a warrant exercise transaction in January 2020, a public offering in February 2020, partial exercises in March, April and May 2020 of warrants issued in the February 2020 public offering, and a registered direct offering in June 2020.

The Company's consolidated financial results for the six months ended June 30, 2020 are presented in accordance with US GAAP Reporting Standards.

Conference Call

Management will host a conference call today, August 27, 2020 at 4:15 p.m. ET. Investors in the U.S. are invited to dial 877-423-9813. International investors may dial 201-689-8573. The conference ID is 13708494. Investors may also participate via webcast: http://public.viavid.com/index.php?id=141284

A replay of the webcast will be archived on Can-Fite's website for a period of time.

INTERIM CONSOLIDATED BALANCE SHEETS

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

	June 30, 2020 Unaudited	December 31, 2019 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,059	$ 2,697
Other receivable and prepaid expenses	3,567	4,383
Short-term investment	78	64
Total current assets	12,704	7,144
NON-CURRENT ASSETS:		
Other non-current receivables	-	912
Operating lease right of use assets	66	82
Property, plant and equipment, net	30	36
Total long-term assets	96	1,030
Total assets	$ 12,800	$ 8,174

INTERIM CONSOLIDATED BALANCE SHEETS

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

	June 30,	December 31,

	2020	2019
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 437	$ 2,156
Current maturity of operating lease liability	36	36
Deferred revenues	556	469
Other accounts payable	472	610
Total current liabilities	1,501	3,271
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	22	39
Deferred revenues	2,121	2,422
Total long-term liabilities	2,143	2,461
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CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of NIS 0.25 par value - Authorized: 500,000,000 shares at June 30, 2020 and December 31, 2019; Issued and outstanding: 411,254,463 shares as of June 30, 2020; 120,652,683 shares as of December 31, 2019	29,234	8,225
Additional paid-in capital	98,056	103,401
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(119,261)	(110,311)
Total equity	9,156	2,442
Total liabilities and shareholders' equity	$ 12,800	$ 8,174

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Six months ended June 30,	
	2020	2019
	Unaudited	
Revenues	$ 402	$ 688
Research and development expenses	(7,054)	(3,960)
General and administrative expenses	(1,455)	(1,333)
Operating loss	(8,107)	(4,605)
Total financial expenses, net	(128)	(288)
Net loss	(8,235)	(4,893)
Total comprehensive loss	(8,235)	(4,893)
Deemed dividend	(715)	-
Net loss attributed to ordinary shareholders	$ (8,950)	$ (4,893)
Basic and diluted net loss per share	(0.04)	(0.08)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	254,940,675	59,321,108

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, inflammatory disease, and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint in a Phase II trial for the treatment of non-alcoholic steatohepatitis (NASH). 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, market risks and uncertainties, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. 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. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. 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 risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: 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 impact of the recent outbreak of coronavirus; 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; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed in Can-Fite's filings with the SEC and in its periodic filings with the TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

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