June 1, 2020

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

- ***Company to host conference call at 8:30 a.m. ET today, June 1***
- ***Achieved efficacy and safety endpoints in Phase II NASH trial, with all cases of NASH significantly resolved after 12 weeks of treatment with 25 mg Namodenoson***
- ***Pre-IND filed with FDA for clinical study of Piclidenoson in treatment of COVID-19***
- ***Interim results from Phase III Piclidenoson trial for psoriasis and rheumatoid arthritis expected Q4 2020***

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 three months ended March 31, 2020.

Clinical Developments and Corporate Highlights Include:

Namodenoson Showed Significant Efficacy in Phase II NASH Study Including Resolving All Cases of NASH – Can-Fite's Phase II NASH study achieved efficacy and safety endpoints in a dose dependent and statistically significant manner. The double-blind, placebo-controlled, dose-finding efficacy and safety study enrolled 60 patients with non-alcoholic fatty liver disease (NAFLD) with or without non-alcoholic steatohepatitis (NASH). The optimal dosage was determined to be 25 mg for both safety and efficacy. Namodenoson was found to resolve significantly all cases of NASH, representing 25% of the 25 mg treated group, as compared to an increase in new NASH cases in the placebo group from a baseline of 0 to 5.9%. Namodenoson was determined to be a very strong candidate for continued clinical development in the treatment of NAFLD/NASH, particularly since no other treatment options are currently approved for this growing unmet need.

Piclidenoson as Potential Treatment for COVID-19 – Can-Fite filed a pre-Investigational New Drug (IND) meeting request with the U.S. Food and Drug Administration (FDA) for Piclidenoson in the treatment of COVID-19 patients with moderate-to-severe symptoms. Following the FDA's guidance from the pre-IND meeting, Can-Fite plans to submit an IND application for Piclidenoson to be evaluated as a potential addition to the current standard of care treatment for COVID-19. During the first quarter, Can-Fite also entered into a collaborative research agreement with the Lewis Katz School of Medicine at Temple University, Philadelphia to study the anti-viral activity of Piclidenoson on COVID-19 viral load. Can-Fite previously announced that it was approved to commence a COVID-19 clinical study in Israel. While Can-Fite commenced the trial, it has not enrolled patients due to the decreased number of COVID-19 cases in Israel.

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 announced it is implementing an interim analysis for both studies. Data will be monitored by an independent data monitoring committee (IDMC) which will have un-blinded access to the data in Q3 2020. Announcement of interim results is expected in Q4 2020.

Namodenoson is Headed into Pivotal Phase III Liver Cancer Study– Following a successful End-of-Phase II Meeting with the U.S. Food and Drug Administration (FDA) regarding Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer, the FDA agreed with Can-Fite's proposed pivotal Phase III trial design to support a New Drug Application submission and approval. The Phase III study protocol and registration plan have also been submitted to the European Medicines Agency (EMA). Namodenoson is currently being used to treat liver cancer patients in a compassionate use program in Israel, which has enrolled seven patients. In addition, two patients who were enrolled in the Company's former Phase II study, who responded well to the drug, are continuing treatment. Those two advanced liver cancer patients have reached an overall survival of over 2.5 years while being treated with Namodenoson.

Expanded IP – The U.S. Patent and Trademark Office issued a Notice of Allowance to Can-Fite for Namodenoson in the treatment of NASH & NAFLD. A patent was issued for Namodenoson in the treatment of NASH in South Korea, where the drug is out-licensed for this indication. Can-Fite has also filed a new patent for Namodenoson to be used as a combination therapy with checkpoint inhibitors for oncology indications. Based on its recent scientific findings in cannabinoid-based drugs, Can-Fite has filed patents for the use of such drugs to treat cancer, autoimmune, inflammatory and metabolic diseases.

Cash Infusion of $8.4 Million – During the first quarter of 2020, Can-Fite received a total of $3.4 million through warrant exercises, and $5 million from an equity offering.

"Namodenoson's Phase II safety and efficacy results in NASH and NAFLD is a significant milestone for our company, and for the medical community seeking a safe and effective treatment for the rapidly growing number of patients diagnosed with fatty liver diseases. The fact that Namodenoson was able to not only reverse, but also resolve NASH in the Phase II NASH patients treated with 25 mg of Namodenoson is very compelling data as we move forward. With recently issued patents for Namodenoson in this indication, we are planning our next advanced stage clinical trial in NASH/NAFLD," stated Can-Fite CEO Pnina Fishman. "For Namodenoson we are also preparing a Phase III study protocol in the treatment of HCC. Piclidenoson is on track for interim Phase III results in rheumatoid arthritis and psoriasis, as well as a potential treatment for COVID-19. Can-Fite has a robust clinical pipeline with significant opportunities for our drugs in multiple indications."

"I am happy to report that our operations have not been materially impacted by the COVID-19 outbreak to date. Our ongoing clinical trials and clinical trial preparation work 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," added Dr. Fishman.

Financial Results

Revenues for the three months ended March 31, 2020 were $ 0.20 million compared to

revenues of $0.30 million during the three months ended March 31, 2019. The decrease in revenues for the first quarter of 2020 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.

Research and development expenses for the three months ended March 31, 2020 were $3.77 million compared with $1.44 million for the same period in 2019. Research and development expenses for the first quarter of 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 enrollment of patients for the Phase III clinical trial of Piclidenoson for the treatment of rheumatoid arthritis and for psoriasis.

General and administrative expenses were $0.70 million for the three months ended March 31, 2020 compared to $0.57 million for the same period in 2019. The increase is primarily due to an increase in professional services and insurance expenses which was partly offset by a decrease in travel expenses.

Financial expense, net for the three months ended March 31, 2020 was $0.07 million compared to financial expense, net of $0.12 million for the same period in 2019. The decrease in financial expense, net in the first quarter of 2020 is primarily due to a decrease in exchange rate expenses.

Can-Fite's net loss for the three months ended March 31, 2020 was $4.34 million compared with a net loss of $1.83 million for the same period in 2019. As of March 31, 2020, Can-Fite had cash and cash equivalents of $5.76 million as compared to $2.7 million at December 31, 2019. The increase in cash during the three months ended March 31, 2020 is due to an aggregate of $8.4 million received through the exercise of certain outstanding warrants following their repricing in January 2020, a public offering in February 2020, and the partial exercise, in March 2020, of warrants issued in the February 2020 public offering.

Following the end of the first quarter of 2020, the Company determined to change its accounting method from IFRS to U.S. GAAP and accordingly has reissued its audited financial statements for all periods covered by its 2019 financial statements under U.S. GAAP. A copy of the reissued financial statements and accompanying financial data has been filed with the Securities and Exchange Commission on Form 6-K. The Company's consolidated financial results for the three months ended March 31, 2020 are presented in accordance with US GAAP Reporting Standards.

Conference Call

Management will host a conference call today, June 1, 2020 at 8:30 a.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 13704594. Investors may also participate via webcast: http://public.viavid.com/index.php?id=140108

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

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	March 31, 2020 Unaudited	December 31, 2019 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,767	$ 2,697
Other receivable and prepaid expenses	2,730	4,383
Short-term investment	46	64
Total current assets	8,543	7,144
NON-CURRENT ASSETS:		
Other non-current receivables	1,198	912
Operating lease right of use assets	74	82
Property, plant and equipment, net	33	36
Total long-term assets	1,305	1,030
Total assets	$ 9,848	$ 8,174

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

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

	March 31, 2020 Unaudited	December 31, 2019 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,425	$ 2,156
Current maturity of operating lease liability	36	36

Deferred revenues	511	469
Other accounts payable	501	610
Total current liabilities	2,473	3,271
NON-CURRENT LIABILITIES:		
Long - term operating lease liability	29	39
Deferred revenues	2,277	2,422
Total long-term liabilities	2,306	2,461
CONTIGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares of NIS 0.25 par value - Authorized: 500,000,000 shares at March 31, 2020 and December 31, 2019; Issued and outstanding: 263,181,243 shares as of March 31, 2020; 120,652,683 shares as of December 31, 2019	18,560	8,225
Additional paid-in capital	100,750	103,401
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(115,368)	(110,311)
Total equity	5,069	2,442
Total liabilities and shareholders' equity	$ 9,848	$ 8,174

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	1
Revenues	$
Research and development expenses	
General and administrative expenses	
Operating loss	
Total financial expense, net	

Net loss	
Deemed dividend	
Net loss applicable to shareholders' of Ordinary shares	$
Basic and diluted net loss per share	
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	20

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, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is 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 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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