

Can-Fite Reports Second Quarter 2019 Financial Results & Provides Clinical Update

- *Upfront payments received from licensing deals in South Korea for Piclidenoson and Namodenoson with upfront and milestone payments of up to \$10 million plus transfer pricing*
- *Preparatory work for an End of Phase II meeting with FDA to initiate Phase III study in liver cancer is ongoing*
- *Patient enrollment continues in two Phase III studies for Piclidenoson in the treatment of rheumatoid arthritis and psoriasis*
- *Top-line data from Phase II NASH study with Namodenoson expected Q4 2019*

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, 2019.

Clinical Development and Corporate Highlights During Q2 2019 Include:

- **Received Payments for New Distribution Deals for Piclidenoson and Namodenoson in South Korea** – During the second quarter, Chong Kun Dang Pharmaceuticals (CKD) paid Can-Fite \$1,000,000 upfront, with up to an additional \$5,000,000 due upon completion of milestones, plus transfer pricing on the drug for an expanded distribution deal for Namodenoson in South Korea for the indication of NASH. This expanded distribution deal, which was signed in the first quarter of 2019, expands upon the original agreement between Can-Fite and CKD for Namodenoson in the treatment of liver cancer in South Korea. Additionally, in the weeks following the end of the second quarter, Can-Fite entered into an exclusive distribution agreement with Kyongbo Pharm for Piclidenoson in the treatment of psoriasis in South Korea in a deal with upfront and milestone payments of up to \$4,000,000 plus transfer pricing on the drug, upon regulatory approval in South Korea. Can-Fite received an upfront payment of \$750,000 from Kyongbo Pharm.
- **Preparing for End-of-Phase II Study and Initiation of Planned Phase III for Namodenoson in Liver Cancer** - The Company is now preparing for an end-of-Phase II meeting with the FDA in which Can-Fite will review the data from its recently completed Phase II study in patients with hepatocellular cancer (HCC), the most common form of liver cancer, and present the design of its planned Phase III trial, which it expects to initiate following agreement with the FDA. Namodenoson is approved and available for use under Compassionate Use guidelines for the treatment of advanced liver cancer in Israel with patients at the Rabin Medical Center by key

opinion leader Salomon M. Stemmer, MD, Principal Investigator of the Company's completed Phase II liver cancer study.

- **Phase II Liver Cancer Data Presented at ASCO-** Data from Can-Fite's recently completed Phase II trial in patients with HCC was presented at the late-breaking abstract session of the 54th Annual Meeting of the American Society of Clinical Oncology (ASCO), the world's largest clinical cancer research meeting. The most impressive finding was that in the largest subgroup of patients, those with Child Pugh B7, 44% of the patients treated with Namodenoson were alive at one-year post treatment compared to 18% in the placebo group, despite the trial not achieving its primary endpoint.
- **Anti-NASH Effects of Namodenoson Presented at the International Conference on Fatty Liver** – Can-Fite presented compelling preclinical data showing Namodenoson improved liver function through its anti-inflammatory, anti-fibrotic, and anti-steatotic effects at a podium presentation in a session 'Selected Abstracts of Excellence'. The presentation titled, "Namodenoson anti-NAFLD/NASH Activity is Mediated via De-regulation of the Wnt/ β -catenin Pathway" was delivered at the 2nd Annual International Conference on Fatty Liver (ICFL 2019) in Berlin.
- **Phase II Liver Cancer Data Accepted for Presentation at ILCA Conference-** Findings from Can-Fite's Phase II study in liver cancer have been accepted for presentation at the International Liver Cancer Association (ILCA) annual meeting which brings together the leading thought leaders, researchers, and physicians in the treatment of liver cancer. Can-Fite is scheduled to deliver an oral presentation titled, "The Safety and Efficacy of Namodenoson in the Second Line Treatment of Advanced Hepatocellular Carcinoma (HCC) Patients with Underlying Child-Pugh B (CPB) Liver Cirrhosis: A Phase 2, Randomized, Double-Blind, Placebo-Controlled" on September 22, 2019.
- **Cash Infusion of \$11 Million from Distribution Deals and Equity Raise**– During the second quarter, Can-Fite raised a total of \$9,200,000 through two equity offerings in April and May. Additionally, the Company received up-front payments from distribution agreement for its drugs in specific territories and indications in the amount of \$1,000,000, during the second quarter and \$750,000 following the end of the second quarter.

"As we advance our clinical pipeline into Phase III studies, the demand for safe and effective drugs in our chosen indications is evidenced through the distribution agreements that we continue to enter for Piclidenoson and Namodenoson in the global market. In the coming months, we expect to announce top line results from our Phase II study of Namodenoson in the treatment of NASH," stated Can-Fite CEO Prina Fishman.

Financial Results

Revenues for the six months ended June 30, 2019 were \$0.7 million compared to revenues of \$0.9 million during the first six months of 2018. The decrease in revenues was mainly due to the recognition of a higher portion of the \$2.2 million advance payment received in January 2018 under the distribution agreement with Gebro in the six month period ended June 30, 2018.

Research and development expenses for the six months ended June 30, 2019 were \$3.9 million compared with \$2.6 million for the same period of 2018. Research and development expenses for the first six months of 2019 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 initiation of the Phase III clinical trial of Piclidenoson for the treatment of rheumatoid arthritis.

General and administrative expenses were \$1.3 million for the six months ended June 30, 2019 compared to \$1.8 million for the same period in 2018. The decrease is primarily due to a decrease in professional services and investor relations expenses.

Financial expense, net for the six months ended June 30, 2019 was \$0.3 million compared to financial income, net of \$0.6 million for the same period in 2018. The increase in financial expense, net in the first six months of 2019 is mainly due to fair value revaluation of the Wize Pharma Inc. shares which are classified under short term investment.

Can-Fite's net loss for the six months ended June 30, 2019 was \$4.9 million compared with a net loss of \$3.0 million for the same period in 2018. As of June 30, 2019, Can-Fite had cash and cash equivalents of \$8.2 million as compared to \$3.62 million at December 31, 2018. The increase in cash during the six months ended June 30, 2019 is due to net cash provided by financing activity of \$10.1 million which was offset by net cash used in operating activity of \$5.5 million. As of the date hereof, the Company estimates that it has approximately \$6 million in cash and cash equivalents.

In April and May 2019, the Company raised \$3.2 million and \$6 million in gross proceeds, respectively, in registered direct offerings.

The Company's consolidated financial results for the six months ended June 30, 2019 are presented in accordance with International Financial Reporting Standards.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	June 30,	December
	2019	31,
	Unaudited	2018
		Audited
	USD	

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	8,202	3,615
Other receivable and prepaid expenses	5,239	4,015

Short-term investment	<u>178</u>	<u>273</u>
<u>Total current assets</u>	<u>13,619</u>	<u>7,903</u>
NON-CURRENT ASSETS:		
Lease deposits	8	2
Property, plant and equipment, net	<u>40</u>	<u>47</u>
Total long-term assets	<u>48</u>	<u>49</u>
<u>Total assets</u>	<u>13,667</u>	<u>7,952</u>

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

<u>June 30,</u>	<u>December 31,</u>
<u>2019</u>	<u>2018</u>
<u>Unaudited</u>	<u>Audited</u>
<u>USD</u>	

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	\$ 1,510	\$ 1,071
Deferred revenues	1,963	926
Other accounts payable	<u>445</u>	<u>1,122</u>
<u>Total current liabilities</u>	<u>3,918</u>	<u>3,119</u>

NON-CURRENT LIABILITIES:

Deferred revenues	<u>1,308</u>	<u>1,818</u>
<u>Total long-term liabilities</u>	<u>1,308</u>	<u>1,818</u>

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	6,747	2,635
Share premium	100,132	* 94,076
Capital reserve from share-based payment transactions	5,951	5,800
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	<u>(105,516)</u>	<u>(100,623)</u>
Total equity	<u>8,441</u>	<u>3,015</u>
Total liabilities and equity	<u>\$ 13,667</u>	<u>\$ 7,952</u>

(*) Warrants exercisable into shares as of December 31, 2018 were reclassified into Share premium.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

	Six months ended June 30,	
	2019	2018
	Unaudited	
	USD	
Revenues	\$ 688	\$ 902
Research and development expenses	(3,960)	(2,638)
General and administrative expenses	<u>(1,333)</u>	<u>(1,819)</u>
Operating loss	<u>(4,605)</u>	<u>(3,555)</u>
Finance expenses	(324)	(346)
Finance income	<u>36</u>	<u>936</u>
Total financial income (expenses), net	<u>(288)</u>	<u>590</u>
Net loss	<u>(4,893)</u>	<u>(2,965)</u>
Net loss per share attributable to equity holders of the Company		
:		
Basic and diluted net loss per share	<u>(0.08)</u>	<u>(0.08)</u>

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 in preclinical studies and the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. These drugs have an excellent safety profile with experience in over 1,000 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 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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