

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

- *Reached agreement with U.S. FDA on Phase III liver cancer study design & initiated compassionate use program in Israel*
- *Signed new distribution deal for Piclidenoson in South Korea*
- *Entered into strategic agreement to develop cannabinoid-based pharmaceuticals and assays*

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 nine months ended September 30, 2019.

Clinical and corporate developments during Q3 2019 and shortly after the end of the quarter include:

- **Reached Agreement with U.S. FDA on Phase III Study Design for Namodenoson in Liver Cancer** – Can-Fite concluded a successful End-of-Phase II Meeting with the U.S. Food and Drug Administration (FDA) regarding its recently completed Phase II study of Namodenoson in the treatment of hepatocellular cancer (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 design is now being finalized based on guidance from the FDA, and Can-Fite expects to initiate the study in the second half of 2020.
- **Treating Liver Cancer Patients Under Compassionate Use**– Can-Fite enrolled and started treating HCC patients with Namodenoson under its compassionate use program at the Rabin Medical Center in Israel. The approved compassionate use program gives HCC patients early access to treatment with Namodenoson when patients have exhausted other available treatment options.
- **Completed Patient Enrollment in Phase II NASH Study**– Can-Fite completed enrollment of 60 patients with NAFLD (non-alcoholic fatty liver disease) with or without NASH (non-alcoholic steatohepatitis). The Company plans to announce topline results in the first quarter of 2020
- **Signed Distribution Deal for Piclidenoson in South Korea & Received Upfront Payment** – Can-Fite entered into an exclusive distribution agreement with Kyongbo Pharm for Piclidenoson in the treatment of psoriasis in South Korea. Can-Fite received an upfront payment of \$750,000, and the agreement includes milestone payments of up to \$3,250,000 plus transfer pricing on the drug, upon regulatory approval in South

Korea.

- **Enrolling Patients in Phase III Studies for Piclidenoson in Rheumatoid Arthritis and Psoriasis** -- Can-Fite and Gebro Pharma conducted an International Advisory Board conference for the development and commercialization of Piclidenoson with a panel of Key Opinion Leaders in rheumatoid arthritis from Austria, Switzerland, and Spain, the markets for which Gebro has licensed the distribution rights to Piclidenoson for rheumatoid arthritis and psoriasis. Can-Fite is currently enrolling and treating patients in Phase III global studies for these two indications.
- **Entered Collaboration Agreement to Develop Cannabinoid-Based Pharmaceuticals and Assays** – Can-Fite signed an agreement with Univo Pharmaceuticals (TASE:UNVO), a medical cannabis company, to identify and co-develop specific formulations of cannabis components for the treatment of cancer, inflammatory, autoimmune, and metabolic diseases. Can-Fite will contribute its unparalleled expertise in A2AR, which binds with cannabinoids, and is the target of Can-Fite's technology platform. The transaction involves technology exchange, co-development, and revenue share on CBD-based pharmaceuticals and CBD-based A3AR assays.
- **Granted Patents for Sexual Dysfunction Drug, Evaluating Strategic Partnerships** - Can-Fite increased its patent portfolio for its drug candidate CF602 in the treatment of sexual dysfunction. Patents were recently granted in Canada, South Korea, and Israel for its patent titled, "A3 adenosine receptor ligands for use in treatment of a sexual dysfunction". CF602 has a unique mechanism of action that makes it suitable to potentially treat sexual dysfunction safely in patients with diabetes mellitus, a clear and unmet need in the market today. Can-Fite is actively looking for and evaluating potential strategic partners that may in-license and develop CF602 in this indication.

"We are very pleased with the outcome of our End-of-Phase II meeting with FDA regarding Namodenoson in the treatment of liver cancer. As we advance towards a pivotal Phase III study in liver cancer, HCC patients in Israel now have access to Namodenoson through our approved compassionate use program. We look forward to several milestones in 2020, including topline results from our Phase II NASH study, initiation of our Phase III liver cancer study, ongoing enrollment in our Phase III studies for Piclidenoson, as well as our development agreement with Univo, to develop cannabis derived pharmaceuticals and screening based assays" stated Can-Fite CEO Pnina Fishman.

Financial Results

Revenues for the nine months ended September 30, 2019 were \$1.84 million compared with \$3.53 million for the same period of 2018. The decrease in revenues was mainly due to the recognition of \$2 million advance payment received in August 2018 under the distribution agreement with CMS Medical.

Research and development expenses for the nine months ended September 30, 2019 were \$7.01 million compared with \$4.05 million for the same period of 2018. Research and development expenses for the nine months ended 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 \$2.22 million for the nine months ended September 30, 2019 compared to \$2.39 million for the same period in 2018. The decrease is primarily due to a decrease in professional services and investor relations an expense which was partly offset by an increase in insurance expenses.

Financial income, net for the nine months ended September 30, 2019 was \$0.44 million compared to financial income, net of \$0.23 million for the same period in 2018. The increase in financial income, net is mainly due to fair value revaluation of the investment in Wize Pharma's shares which is classified under short term investment.

Can-Fite's net loss for the nine months ended September 30, 2019 was \$7.84 million compared with a net loss of \$3.14 million for the same period in 2018. As of September 30, 2019, Can-Fite had cash and cash equivalents of \$4.68 million as compared to \$3.62 million at December 31, 2018. The increase in cash and cash equivalents is due to net cash provided by financing activity of \$10.1 million which was offset by net cash used in operating activity of \$9.1 million.

The Company's consolidated financial results for the nine months ended September 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)

	September 30, 2019 Unaudited	December 31, 2018 Audited
	USD	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	4,682	3,615
Other receivable and prepaid expenses	5,160	4,015
Short-term investment	111	273
Total current assets	9,953	7,903
NON-CURRENT ASSETS:		
Other receivables	1,750	-

Lease deposits	11	2
Property, plant and equipment, net	<u>37</u>	<u>47</u>
Total long-term assets	<u>1,798</u>	<u>49</u>
Total assets	<u><u>11,751</u></u>	<u><u>7,952</u></u>

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

September 30, 2019 Unaudited	December 31, 2018 Audited
USD	

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	\$ 1,364	\$ 1,071
Deferred revenues	1,410	926
Other accounts payable	<u>351</u>	<u>1,122</u>
Total current liabilities	<u>3,125</u>	<u>3,119</u>

NON-CURRENT LIABILITIES:

Deferred revenues	<u>1,570</u>	<u>1,818</u>
Total long-term liabilities	<u>1,570</u>	<u>1,818</u>

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	8,153	2,635
Share premium	100,225	* 94,076
Capital reserve from share-based payment transactions	6,015	5,800
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	<u>(108,464)</u>	<u>(100,623)</u>

Total equity	7,056	3,015
Total liabilities and equity	<u>\$ 11,751</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)

	Nine months ended September 30, 2019 2018 Unaudited USD	
Revenues	\$ 1,840	\$ 3,531
Research and development expenses	(7,016)	(4,056)
General and administrative expenses	<u>(2,220)</u>	<u>(2,386)</u>
Operating loss	<u>(7,396)</u>	<u>(2,911)</u>
Finance expenses	(508)	(428)
Finance income	<u>63</u>	<u>197</u>
Total financial income (expenses), net	<u>(445)</u>	<u>(231)</u>
Net loss	<u><u>(7,841)</u></u>	<u><u>(3,142)</u></u>
Net loss per share attributable to equity holders of the Company		
:		
Basic and diluted net loss per share	<u><u>(0.11)</u></u>	<u><u>(0.08)</u></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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