

March 27, 2020

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# Can-Fite Reports 2019 Financial Results & Provides Clinical Development Update

- *Piclidenoson has been submitted for the treatment of coronavirus under compassionate use program in Israel*
- *Top-line data from Phase II Namodenoson trial for NASH expected during April 2020*
- *Interim results from Phase III Piclidenoson trial for 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 year ended December 31, 2019.

Clinical Developments and Corporate Highlights Include:

**Piclidenoson as Potential Treatment for Coronavirus**– Piclidenoson’s anti-rheumatic and anti-viral effects, combined with its excellent safety profile, make it a potential candidate for the treatment of coronavirus. Can-Fite recently submitted Piclidenoson to the Institutional Review Board at Rabin Medical Center for a compassionate use program to treat coronavirus patients. If approved, the compassionate use program will be led by Dr. Dror Diker, M.D., Head of Internal Medicine D at the Rabin Medical Center. Concurrently, through a collaborative research agreement with the Lewis Katz School of Medicine at Temple University in Philadelphia, Can-Fite is conducting studies on the anti-viral activity of Piclidenoson on the coronavirus. The anti-viral effect of Piclidenoson is protected by US patent US7589075. Rheumatoid arthritis drugs are now being evaluated for the treatment of coronavirus in global studies, and China recently approved the use of Roche’s Actemra, a rheumatoid arthritis drug, to treat coronavirus.

**Namodenoson Phase II NASH Data Expected in April 2020**- Can-Fite completed enrollment of 60 patients with NAFLD (non-alcoholic fatty liver disease) with or without NASH (non-alcoholic steatohepatitis), and plans to announce topline results during April 2020. The end points of this study include serum ALT levels, percentage change in liver fat, as measured by PDFF (proton density fat fraction), weight loss and additional serum parameters.

**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.

### **Piclidenoson Phase III Rheumatoid Arthritis and Psoriasis Studies Complete 50% Enrollment; Interim Data for Rheumatoid Arthritis Expected Q4 2020**

- Can-Fite continues to enroll patients in its Phase III study for psoriasis. An interim analysis is being implemented for the rheumatoid arthritis study. Data will be monitored by an independent data monitoring committee (IDMC) which will have un-blinded access to the data in Q3 2020, with an announcement of interim results expected in Q4 2020.

**Developing Cannabinoid-based Drug Candidates** – During 2019, 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 diseases in which there is an overexpression of A3AR, Can-Fite's target. Based on its recent scientific findings, Can-Fite has filed patents for the use of cannabinoid-based drugs to treat cancer, autoimmune, inflammatory and metabolic diseases. The Company's most recent research revealed that cannabis-derived CBD enriched fractions inhibit fat cell expansion and have beneficial effects against liver cancer.

**Cash Infusion of \$11 Million from Distribution Deals and Equity Raise**– During 2019, Can-Fite raised a total of \$9.2 million through equity offerings, and received upfront payments from distribution agreements for its drugs in specific territories and indications in the amount of \$1.75 million. The upfront payments from distributors were part of agreements that totaled \$10 million plus royalties based on the achievement of milestones. Following the end of 2019, Can-Fite received an additional cash infusion of \$8.4 million through a combination of \$5 million raised through an equity offering and \$3.4 million through cash exercises of warrants.

“We are focused on delivering our advanced stage drug candidates to meet the immediate medical needs of patients who lack safe and effective treatments to life threatening conditions. This includes Piclidenoson for the treatment of coronavirus and Namodenoson for advanced liver cancer,” stated Can-Fite CEO Pnina Fishman. “In 2019, we achieved very significant progress in our Phase III trials of Piclidenoson and are now over 50% complete with patient enrollment. In 2020, we are well positioned for achieving milestones which we believe may generate more non-dilutive funding for Can-Fite through new global distribution agreements, as well as trigger milestone payments from our current agreements.”

### **Financial Results**

Revenues for the year ended December 31, 2019 were \$2.0 million, a decrease of \$1.8 million, or 47.3%, compared to \$3.8 million for the year ended December 31, 2018. The decrease in revenue was mainly due to the recognition of a \$2 million advance payment received in August 2018 under the License, Collaboration and Distribution Agreement with CMS Medical.

Research and development expenses for the year ended December 31, 2019 were \$10.9 million, an increase of \$4.9 million, or 81.6%, compared to \$6 million for the year ended December 31, 2018. Research and developments expenses for the year ended 2019 comprised primarily of expenses associated with the Phase II studies for Namodenoson and

Phase III studies of Piclidenoson. 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. We expect that the research and development expenses will increase through 2020 and beyond.

General and administrative expenses were \$3.0 million for the year ended December 31, 2019 a decrease of \$0.1 million, or 3.1%, compared to \$3.1 million for the year ended December 31, 2018. The decrease is primarily due to decrease in investor relations expense and a decrease in salary and related expenses which was partly offset by an increase in insurance expenses. We expect that general and administrative expenses will remain at the same level through 2020.

Financial income, net for the year ended December 31, 2019 were \$2.4 million compared to financial expenses, net of \$1.1 million in the same period in 2018. The decrease in financial expense, net was mainly due to decrease in a loss from short-term investment revaluation and increase in income from changes in fair value of warrants liability exercisable into shares.

Net loss for the year ended December 31, 2019 was \$9.5 million compared with a net loss of \$6.6 million for the year ended December 31, 2018. The increase in net loss for the year ended December 31, 2019 was primarily attributable to decrease in revenues in 2019 and an increase in research and development expenses which were partly offset by an increase in finance income, net.

As of December 31, 2019, Can-Fite had cash and cash equivalents of \$2.7 million as compared to \$3.6 million at December 31, 2018. The decrease in cash during the year ended December 31, 2019 is due to increase in net cash provided by financing activity which was offset by an increase in net cash used in operating activity. In February 2020, Can-Fite raised \$5 million in a registered direct offering, and in January and March 2019 the Company received approximately \$3.4 million through warrant exercises.

More detailed information can be found in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, a copy of which has been filed with the Securities and Exchange Commission (SEC). The Annual Report, which contains the Company's audited consolidated financial statements, can be accessed on the SEC's website at <http://www.sec.gov/> as well as via the Company's investor relations website at <https://ir.canfite.com>. The Company will deliver a hard copy of its Annual Report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Can-Fite Investor Relations at 10 Bareket Street, Kiryat Matalon, Petah-Tikva 4951778, Israel or by phone at +972-3-9241114.

## **CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

**In thousands (except for share and per share data)**

<b>December 31,</b>	
<b>2019</b>	<b>2018</b>
<b>USD</b>	

ASSETS

**CURRENT ASSETS:**

Cash and cash equivalents	\$2,697	\$3,615
Other accounts receivables and prepaid expenses	4,383	4,015
Short-term investment	64	273

<u>Total</u> current assets	<u>7,144</u>	<u>7,903</u>
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**NON-CURRENT ASSETS:**

Lease deposit	-	2
Other non-current receivables	912	-
Right to use asset	83	-
Property, plant and equipment, net	36	47

<u>Total</u> long-term assets	<u>1,031</u>	<u>49</u>
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<u>Total</u> assets	<u>\$8,175</u>	<u>\$7,952</u>
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**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

In thousands (except for share and per share data)

December 31,

2019      2018

USD

**LIABILITIES AND SHAREHOLDERS' EQUITY****CURRENT LIABILITIES:**

Trade payables	\$ 2,156	\$ 1,071
Lease liability - current	36	-
Deferred revenues	469	926
Other accounts payable	610	1,122

<u>Total</u> current liabilities	<u>3,271</u>	<u>3,119</u>
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**NON-CURRENT LIABILITIES:**

Lease liability – non current	39	-
Warrants exercisable into shares	1,566	-
Deferred revenues	2,422	1,818

<u>Total</u> Long-term liabilities	<u>4,027</u>	<u>1,818</u>
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**CONTINGENT LIABILITIES AND COMMITMENTS**

**EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:**

Share capital	8,225	2,635
Share premium	95,665	94,076
Capital reserve from share-based payment transactions	6,070	5,800
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	<u>(110,210)</u>	<u>(100,623)</u>
<b>Total equity</b>	<b>877</b>	<b>3,015</b>
<b>Total liabilities and equity</b>	<b>\$ 8,175</b>	<b>\$ 7,952</b>

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**In thousands (except for share and per share data)**

	<b>Year ended December 31,</b>		
	<b>2019</b>	<b>2018</b>	<b>2017</b>
	<b>USD</b>		
Revenues	\$ 2,032	\$ 3,820	\$ 789
Research and development expenses	(10,976)	(6,075)	(5,106)
General and administrative expenses	<u>(3,059)</u>	<u>(3,159)</u>	<u>(2,868)</u>
Operating loss	<u>(12,003)</u>	<u>(5,414)</u>	<u>(7,185)</u>
Other income		-	769
Financial expenses	(693)	(1,204)	(621)
Financial income	<u>3,109</u>	<u>51</u>	<u>633</u>
Total Financial income (expense), net	<u>2,416</u>	<u>(1,153)</u>	<u>12</u>
Loss before taxes on income	(9,587)	(6,567)	(6,404)
Taxes on income	<u>-</u>	<u>(4)</u>	<u>(29)</u>
Net loss	<u>(9,587)</u>	<u>(6,571)</u>	<u>(6,433)</u>
Other comprehensive loss:			

Amounts that will not be reclassified subsequently to profit or loss:

Adjustment arising from translating financial statements from functional currency to presentation currency	-	-	636
Total other comprehensive loss	-	-	636
Total comprehensive loss	<u>\$ (9,587)</u>	<u>\$(6,571)</u>	<u>\$(5,797)</u>
Net loss Attributable to:			
Equity holders of the Company	\$ (9,587)	\$(6,571)	\$(6,339)
Non-controlling interests	-	-	(94)
	(9,587)	(6,571)	(6,433)
Total comprehensive loss attributable to:			
Equity holders of the Company	(9,587)	(6,571)	(5,703)
Non-controlling interests	-	-	(94)
	<u>\$ (9,587)</u>	<u>\$(6,571)</u>	<u>\$(5,797)</u>
Net loss per share attributable to equity holders of the Company:			
Basic and diluted net loss per share	<u>\$ (0.11)</u>	<u>\$(0.17)</u>	<u>\$(0.19)</u>

### Important Message Regarding COVID-19

Public health epidemics or outbreaks could adversely impact our business. In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China. While initially the outbreak was largely concentrated in China, it has now spread to several other countries, including in Israel, and infections have been reported globally. The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of the coronavirus globally, could adversely impact our operations and workforce, including our research and clinical trials and our ability to raise capital, which in turn could have an adverse impact on our business, financial condition and results of operation.

### 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](http://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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