

Can-Fite Reports Third Quarter 2017 Financial Results & Provides Clinical Update

- **Namodenoson:**
 - *Commences enrollment in Phase II NAFLD/NASH trial*
 - *Completes enrollment in Phase II liver cancer trial*
 - *Receives milestones payment from Korean distributor*
- **Piclidenoson:**
 - *Commences enrollment in Phase III rheumatoid arthritis trial as a replacement for standard of care MTX*

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE MKT:CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, today reported financial results for the nine months ended September 30, 2017 and provided clinical and corporate updates.

Clinical Development Program and Corporate Highlights Include:

Namodenoson (CF102): Advances Phase II Trials and Receives Milestone Payment

- **First Patient Enrolled in Phase II Trial for Treatment of NAFLD/NASH**

Patient enrollment has commenced in Can-Fite's Phase II trial of Namodenoson in the treatment of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). The 12-week trial is enrolling approximately 60 patients and is estimated to cost less than \$1 million. There is currently no U.S. FDA approved drug for the indication of NASH, which is an addressable pharmaceutical market estimated to reach \$35-40 billion by 2025.

- **Milestone Payment Received for Distribution of Namodenoson in Korea for the Treatment of Liver Cancer**

During the third quarter of 2017, Can-Fite received a milestone payment of \$500,000 from Chong Kun Dang Pharmaceuticals (CKD), which licensed the exclusive right to distribute Namodenoson for the treatment of liver cancer in Korea upon receipt of regulatory approvals. The payment is part of a deal worth up to \$3,000,000 in upfront and milestone payments plus 23% royalties.

- **Patient Enrollment Completed in Phase II Liver Cancer Trial of Namodenoson**

Can-Fite completed enrollment during the third quarter of 2017 and randomized all 78 patients in its global Phase II study of Namodenoson in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. Patients with advanced HCC,

Child Pugh B, were enrolled in the U.S., Europe and Israel. The primary endpoint of the Phase II study is overall survival. Can-Fite is following the survival data closely and plans to perform the survival analysis at the earliest possible opportunity. The HCC market is expected to generate \$1.4 billion in sales in 2019.

- **Data Presented on Namodenoson at NASH Summit Europe and The Liver Meeting®**

Dr. Pnina Fishman, Can-Fite's CEO, joined global thought-leaders in the treatment of NASH at the NASH Summit Europe in October, in Frankfurt, Germany, where she delivered a presentation titled, "The Anti-Fibrogenic and Liver Protective Effects of Namodenoson (CF102): From Preclinical to Human Studies."

Can-Fite also presented two scientific posters at the American Association for the Study of Liver Diseases (AASLD) annual conference, The Liver Meeting® in Washington, D.C. in October. The posters were titled "Namodenoson (CF102) Prevents Liver Fibrosis in the CCL4 Model" and "The Anti-Fibrogenic and Liver Protective Effects of Namodenoson (CF102) in a Non-Alcoholic Steatohepatitis model."

Piclidenoson (CF101): Commences Patient Enrollment and Dosing in ACRobat Phase III Trial in Rheumatoid Arthritis

Patient enrollment and dosing has commenced in Can-Fite's Phase III ACRobat trial that is evaluating Piclidenoson as a first line treatment and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis. The trial is enrolling approximately 500 patients in Europe, Canada and Israel. The estimated cost of the entire 24-week Phase III study is approximately \$5 million. An estimated 90% of rheumatoid arthritis patients receive MTX at some point in their disease. However, studies show that up to 50% of patients stop taking MTX due to reasons including drug intolerance, minor and major side effects, and lack of efficacy, creating a significant need for a new, safe and effective treatment option in the rheumatoid arthritis treatment market which is forecast to reach \$34.6 billion by 2020.

Can-Fite is also advancing Piclidenoson towards a Phase III trial in the treatment of psoriasis which is expected to commence in 2018. The upcoming trial will investigate the efficacy and safety of Piclidenoson compared to placebo as its primary endpoint and as compared to apremilast (Otezla®) as its secondary endpoint in approximately 400 patients with moderate-to-severe plaque psoriasis. The psoriasis market is forecast to be \$8.9 billion in 2018 and Otezla® sales are estimated to be \$2.35 billion by 2020.

Expands Intellectual Property

Can-Fite was issued a new patent from the Korean Intellectual Property Office for Piclidenoson titled, "Pharmaceutical Composition Comprising A3 Adenosine Receptor Agonist (IB-MECA/CF-101) For Treatment of Psoriasis."

A new patent application was filed by Can-Fite to protect the use of its drugs and other ligands which target the A3 adenosine receptor (A3AR) in the treatment of cytokine release syndrome (CRS), a potentially life-threatening complication of CAR-T cell therapy. CAR-T is viewed by the medical community as a very promising cancer immunotherapy, however,

CRS, which is caused by an overactive immune response to the treatment, has been identified as a potentially severe and life-threatening side effect of CAR-T. Can Fite's platform technology selectively targets A3AR, which plays a central role in mediating the mechanism of inflammation in CRS, and as such, Can-Fite believes that A3AR targeting may serve as an important treatment option for patients in reducing the risk of CRS without limiting the utility of the underlying cancer immunotherapy.

Can-Fite's Former Subsidiary OphthaliX Successfully Completes Merger with Wize Pharma

Can-Fite's former majority-owned subsidiary, OphthaliX Inc. (since renamed Wize Pharma, Inc.) recently completed a merger with Wize Pharma Ltd. As a result of the merger, Can-Fite's ownership of OphthaliX, immediately post-merger, became approximately 8% of the outstanding shares of common stock. In addition, immediately prior to the merger, OphthaliX sold on an "as is" basis to Can-Fite all the ordinary shares of Eyefite Ltd., a former wholly owned subsidiary of OphthaliX, in exchange for the irrevocable cancellation and waiver of all indebtedness owed by OphthaliX and Eyefite to Can-Fite, including approximately \$5 million of deferred payments and, as part of the purchase of Eyefite, Can-Fite also assumed certain accrued milestone payments in the amount of \$175,000 under a license agreement previously entered into with the U.S. National Institutes of Health (NIH). In addition, as a result of the merger, an exclusive license of Piclidenoson (CF101) for the treatment of ophthalmic diseases previously granted by Can-Fite to OphthaliX and a related services agreement was terminated.

"We are pleased to be on target with commencing patient enrollment in our Phase III rheumatoid arthritis and Phase II in NAFLD/NASH studies. Namodenoson is gaining increasing recognition in the medical community, as evidenced by our recent scientific presentations, for its liver protective properties in both NASH and liver cancer. In 2018, we look forward to initiating our Phase III study of Piclidenoson in psoriasis, as well as potentially announcing top line data on our Phase II liver cancer study of Namodenoson," Dr. Fishman stated.

Financial Results

Revenues for the nine months ended September 30, 2017 were NIS 2.61 million (U.S. \$0.74 million) compared to NIS 0.64 million (U.S. \$0.18 million) in the first nine months of 2016. The increase in revenue was mainly due to payment received of NIS 1.8 million (U.S. \$0.5 million) in August 2017 under the distribution agreement with CKD.

Research and development expenses for the nine months ended September 30, 2017 were NIS 12.7 million (U.S. \$3.6 million) compared with NIS 15.45 million (U.S. \$4.38 million) for the same period in 2016. Research and development expenses for the nine months ended September 30, 2017 comprised primarily of expenses associated with the Phase II study for Namodenoson as well as expenses for ongoing studies of Piclidenoson. The decrease is primarily due to a reduction in preclinical studies of CF602 conducted during the nine months ended September 30, 2017.

General and administrative expenses were NIS 7.48 million (U.S. \$2.12 million) for the nine months ended September 30, 2017, compared to NIS 7.88 million (U.S. \$2.23 million) for the same period in 2016. The decrease in general and administrative expenses was mainly due

to a decrease in investor relations expenses.

Financial income, net for the nine months ended September 30, 2017 aggregated NIS 3.91 million (U.S. \$1.11 million) compared to financial income, net of NIS 3.12 million (U.S. \$0.88 million) for the same period in 2016. The increase in financial income, net in the nine months ended September 30, 2017 was mainly from a larger decrease in the fair value of warrants that are accounted for as financial liability as compared to the same period in 2016, offset by exchange rate differences as compared to the same period in 2016 and from issuance expenses.

Can-Fite's net loss for the nine months ended September 30, 2017 was NIS 13.75 million (U.S. \$3.90 million) compared with a net loss of NIS 19.56 million (U.S. \$5.54 million) for the same period in 2016. The decrease in net loss for the nine months ended September 30, 2017 was primarily attributable to a decrease in research and development expenses.

As of September 30, 2017, Can-Fite had cash and cash equivalents of NIS 18.02 million (U.S. \$5.11 million) as compared to NIS 31.2 million (U.S. \$8.84 million) at December 31, 2016. The decrease in cash during the nine months ended September 30, 2017 is due to use of cash to fund operating expenses.

For the convenience of the reader, the reported NIS amounts have been translated into U.S. dollars, at the representative rate of exchange on September 30, 2017 (U.S. \$1 = NIS 3.529).

The Company's consolidated financial results for the nine months ended September 30, 2017 are presented in accordance with International Financial Reporting Standards.

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 a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis in early 2018. Can-Fite's liver cancer drug, Namodenoson, is in Phase II trials for hepatocellular carcinoma (HCC), the most common form of liver cancer, and 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: 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 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; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; 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.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

Convenience translation into U.S. dollars		
September 30, 2017	September 30, 2017	December 31, 2016

	Unaudited		Audited
	USD	NIS	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	5,106	18,018	31,203
Other receivable and prepaid expenses	3,609	12,737	7,664
<u>Total current assets</u>	<u>8,715</u>	<u>30,755</u>	<u>38,867</u>
NON-CURRENT ASSETS:			
Lease deposits	8	28	37
Property, plant and equipment, net	47	168	205
<u>Total long-term assets</u>	<u>55</u>	<u>196</u>	<u>242</u>
<u>Total assets</u>	<u>8,770</u>	<u>30,951</u>	<u>39,109</u>

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September 30, 2017	September 30, 2017	December 31, 2016
Unaudited	Audited	
USD	NIS	

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	416	1,470	4,804
Deferred revenues	302	1,066	1,237

Other accounts payable	662	2,337	3,588
<u>Total current liabilities</u>	<u>1,380</u>	<u>4,873</u>	<u>9,629</u>
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	2,820	9,951	10,068
Deferred revenues	1,100	3,882	4,510
<u>Total long-term liabilities</u>	<u>3,920</u>	<u>13,833</u>	<u>14,578</u>
CONTINGENT LIABILITIES AND COMMITMENTS			
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:			
Share capital	2,349	8,289	7,039
Share premium	96,787	341,561	332,873
Capital reserve from share-based payment transactions	6,141	21,670	20,438
Warrants exercisable into shares (series 10-12)	2,545	8,983	8,983
Treasury shares, at cost	(1,028)	(3,628)	(3,628)
Accumulated other comprehensive loss	(267)	(943)	(883)
Accumulated deficit	(103,060)	(363,699)	(349,953)
<u>Total equity attributable to equity holders of the Company</u>	<u>3,467</u>	<u>12,233</u>	<u>14,869</u>
Non-controlling interests	3	12	33
<u>Total equity</u>	<u>3,470</u>	<u>12,245</u>	<u>14,902</u>
<u>Total liabilities and equity</u>	<u>8,770</u>	<u>30,951</u>	<u>39,109</u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
In thousands (except for share and per share data)

**Convenience
translation
into
U.S. dollars**

	Nine months ended September 30,		
	2017	2017	2016
	Unaudited		
	USD	NIS	NIS
Revenues	740	2,611	643
Research and development expenses	3,598	12,699	15,449
General and administrative expenses	2,120	7,481	7,878
Operating loss	4,978	17,569	22,684
Finance expenses	1,000	3,529	1,411
Finance income	(2,107)	(7,434)	(4,535)
Loss before taxes on income	3,871	13,664	19,560
Taxes on income	26	90	-
Net loss	3,897	13,754	19,560
Other comprehensive loss (income):			
Total components that will be or that have been reclassified to profit or loss:			
Adjustments arising from translating financial statements of foreign operations	21	73	(10)
Total comprehensive loss	3,918	13,827	19,550
Net loss attributable to:			
Equity holders of the Company	3,895	13,746	19,294
Non-controlling interests	2	8	266
	3,897	13,754	19,560
Total comprehensive loss attributable to:			
Equity holders of the Company	3,912	13,806	19,286

Non-controlling interests	<u>6</u>	<u>21</u>	<u>264</u>
	<u>3,918</u>	<u>13,827</u>	<u>19,550</u>
Net loss per share attributable to equity holders of the Company :			
Basic and diluted net loss per share	<u>0.12</u>	<u>0.42</u>	<u>0.70</u>

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