

August 31, 2018

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# Can-Fite Reports Second Quarter 2018 Financial Results and Provides Clinical Update

**- Company signed a multi-million dollar development and distribution agreement for Piclidenoson and Namodenoson in China with CMS Medical and received an upfront payment of \$2M**

**- Piclidenoson Phase III study in psoriasis has been initiated and prompts a regulatory milestone payment**

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 disease and inflammatory diseases, today reported financial results for the three months ended June 30, 2018 and provided clinical and corporate updates.

**Clinical Development Program and Corporate Highlights of the Second Quarter 2018 and Recent Weeks Include:**

## **Business Development Activities Q**

In August 2018, Can-Fite signed a License, Collaboration and Distribution agreement with CMS Medical Venture Investment Limited ("CMS Medical") for the development and commercialization of Can-Fite's Piclidenoson for the treatment of rheumatoid arthritis and psoriasis and Namodenoson for the treatment of advanced liver cancer and NAFLD/NASH in China (including Hong Kong, Macao and Taiwan). Under the terms of the agreement, CMS Medical made an upfront payment of \$2,000,000 to Can-Fite and is required to pay to Can-Fite milestone payments of up to \$14,000,000 upon the achievement of certain regulatory milestones and payments of up to \$58,500,000 upon the achievement of certain sales milestones. In addition, the agreement provides for double-digit royalty payments on net sales.

This deal adds to the distribution agreements that the Company already has in place with Cipher Pharmaceuticals (for the distribution of Piclidenoson in Canada for rheumatoid arthritis and psoriasis), Kwang Dong Pharmaceutical (for the distribution of Piclidenoson in South Korea for rheumatoid arthritis), Chong Kun Dang (for distribution of Namodenoson in South Korea for treatment of liver cancer) and Gebro Pharma (for the distribution of Piclidenoson in Spain, Switzerland and Austria).

## **Intellectual Property**

Can-Fite has been granted by the Australian and Chinese patent offices a patent for the utilization of A3 adenosine receptor ligands in the treatment of sexual dysfunction, in a patent (Australian, No. 2013301125ZL; Chinese No. 2013800472970) titled, "A3adenosine

receptor ligands for use in treatment of a sexual dysfunction." The Company has been investigating compounds that target the A3 adenosine receptor (A3AR) and the Company's CF602 drug candidate previously demonstrated a robust positive effect in the treatment of erectile dysfunction in preclinical studies.

## **Clinical Development Activities**

### **Piclidenoson (CF101)**

Psoriasis – In August 2018, Can-Fite enrolled and dosed the first patient in its Phase III Comfort™ trial for the treatment of moderate-to-severe plaque psoriasis, which makes up about 90 percent of cases. The study, is designed to evaluate the efficacy and safety of daily Piclidenoson, administered orally compared to Apremilast (Otezla®) and placebo, in 407 patients. The study will be conducted in 5 countries in Europe, Israel and Canada. The first patient has been dosed in Israel.

Study initiation prompts a milestone payment of 300,000 Euro that is due under the distribution agreement recently entered into with Gebro.

Rheumatoid Arthritis – The Company continues to enroll patients in its Phase III Acrobat™ trial that is evaluating Can-Fite's lead drug candidate Piclidenoson as a first line treatment and replacement for the current standard of care, Methotrexate (MTX). The trial will enroll approximately 500 patients in Europe, Canada and Israel.

### **Namodenoson (CF102)**

#### Advanced Liver Cancer

In August 2017, Can-Fite completed enrollment of its global Phase II advanced liver cancer study of Namodenoson. In June 2018, the Company reported that the accumulated safety data continues to indicate a favorable safety profile, with no clinically significant novel or emerging events attributed to chronic treatment with Namodenoson. The Company continues to follow up on patients' overall survival.

In July 2018, the Company announced that key opinion leaders from the University of Texas MD Anderson Cancer Center, Houston, TX, USA, published scientific findings recommending development of anti-liver cancer drugs based on a mechanism of action utilized by Namodenoson. The latter inhibits a specific molecular signaling pathway in the liver cancer cells, designated as the Wnt/ $\beta$ -catenin, and is responsible for the development and progression of hepato-cellular carcinoma (HCC).

#### NAFLD/NASH

The Company is continuing to enroll patients for its Phase II trial of Namodenoson for the treatment of 60 patients with nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH).

"We continue to make progress with our drug candidates. We also signed a significant development and commercialization agreement with CMS Medical for both Piclidenoson and Namodenoson for the Chinese market with significant regulatory and sales' milestone payments. We look forward to providing updates on our Phase II study of Namodenoson

towards the end of year,” stated Can-Fite CEO Dr. Pnina Fishman.

## **Financial Results**

Revenues for the six months ended June 30, 2018 were \$0.9 million compared to \$0.1 million in the first six months of 2017. The increase in revenue was mainly due to the recognition of a portion of the U.S. \$2.2 million advance payment received in January 2018 under the distribution agreement with Gebro.

Research and development expenses for the six months ended June 30, 2018 were \$2.6 million compared with \$2.4 million for the same period in 2017. Research and development expenses for the first six months of 2018 comprised primarily of expenses associated with the Phase II studies for Namodenoson as well as expenses for ongoing 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 2018 and beyond.

General and administrative expenses were \$1.8 million for the six months ended June 30, 2018, compared to \$1.3 million for the same period in 2017. The increase is primarily due to an increase in professional services and investor relations expenses. We expect that the annual general and administrative expenses for 2018 will be higher compared to 2017.

Financial income, net for the six months ended June 30, 2018 aggregated \$0.6 million compared to financial income, net of \$0.2 million for the same period in 2017. The increase in financial income, net was mainly due to fair value revaluation of our long-term investment.

Can-Fite's loss for the six months ended June 30, 2018 was U.S. \$3.0 million compared with a loss of U.S. \$3.5 million for the same period in 2017. The difference in loss for the first half of 2018 was primarily attributable to an increase in revenues and an increase in financial income, net.

As of June 30, 2018, Can-Fite had cash and cash equivalents of U.S. \$5.8 million as compared to U.S. \$3.5 million at December 31, 2017. The increase in cash during the six months ended June 30, 2018 is due to U.S. \$4.4 million received from a registered direct offering in March 2018, net of issuance expenses, and the \$2.2 million upfront payment received from Gebro.

The Company's consolidated financial results for the six months ended June 30, 2018 are presented in accordance with International Financial Reporting Standards.

## **INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

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

<b>June 30,</b>	<b>December 31,</b>
<b>2018</b>	<b>2017</b>
<b>Unaudited</b>	
<b>USD</b>	

## ASSETS

### CURRENT ASSETS:

Cash and cash equivalents	\$ 5,840	\$ 3,505
Other receivable and prepaid expenses	<u>3,286</u>	<u>3,159</u>
Total current assets	<u>9,126</u>	<u>6,664</u>

### NON-CURRENT ASSETS:

Lease deposits	5	5
long-term investment	1,829	917
Property, plant and equipment, net	<u>24</u>	<u>28</u>
Total long-term assets	<u>1,858</u>	<u>950</u>
Total assets	<u>\$ 10,984</u>	<u>\$ 7,614</u>

## INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

June 30, 2018	December 31, 2017
Unaudited	
USD	

## LIABILITIES AND SHAREHOLDERS' EQUITY

### CURRENT LIABILITIES:

Trade payables	\$ 668	\$ 427
Deferred revenues	792	330
Other accounts payable	<u>697</u>	<u>997</u>
Total current liabilities	<u>2,157</u>	<u>1,754</u>

### NON-CURRENT LIABILITIES:

Deferred revenues	<u>2,317</u>	<u>846</u>
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Total long-term liabilities	2,317	846
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## CONTINGENT LIABILITIES AND COMMITMENTS

## EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	2,633	2,123
Share premium	81,646	81,104
Capital reserve from share-based payment transactions	5,713	5,547
Warrants exercisable into shares	12,408	8,815
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(97,017)	(93,702)

Total equity	6,510	5,014
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Total liabilities and equity	\$ 10,984	\$ 7,614
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## INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

	Six months ended June 30,	
	2018	2017
	Unaudited	Unaudited
	USD	USD
Revenues	\$ 902	\$ 136
Research and development expenses	2,638	2,436
General and administrative expenses	1,819	1,373
Operating loss	3,555	3,673
Finance expenses	346	305
Finance income	(936)	(463)
Total Financial income, net	(590)	(158)
Loss	2,965	3,515

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	-	(420)
Total other comprehensive loss	<u>\$ 2,965</u>	<u>\$ 3,095</u>

Loss attributable to:

Equity holders of the Company	2,965	3,462
Non-controlling interests	<u>-</u>	<u>53</u>
	<u>\$ 2,965</u>	<u>\$ 3,515</u>

Total comprehensive loss attributable to:

Equity holders of the Company	2,965	3,042
Non-controlling interests	<u>-</u>	<u>53</u>
	<u>\$ 2,965</u>	<u>\$ 3,095</u>

Loss per share attributable to equity holders of the Company :

Basic and diluted loss per share	<u>(0.08)</u>	<u>(0.1)</u>
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#### 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 multibillion-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, 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](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 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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