

June 1, 2018

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

- Company Received upfront payment of \$2.2M as Part of Distribution Agreement for Piclidenoson in 3 European Countries

- Namodenoson Phase II Liver Cancer, Phase II NAFLD/NASH and Phase III Rheumatoid Arthritis studies are Ongoing

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 March 31, 2018 and provided clinical and corporate updates.

Clinical Development Program and Corporate Highlights Include:

- **Piclidenoson (CF101) – Can-Fite continues Phase III trial of Piclidenoson in the treatment of rheumatoid arthritis and signed multi-million dollar distribution agreement with Gebro Holdings for Piclidenoson in three European countries**

Rheumatoid Arthritis: In January 2018, Can-Fite signed a distribution agreement with Gebro Holding GmbH to distribute Can-Fite's lead drug candidate, Piclidenoson (CF101), for the treatment of rheumatoid arthritis and psoriasis, in three European countries (Spain, Switzerland and Austria), upon receipt of regulatory approvals. Under the terms of the distribution agreement, Gebro is required to pay additional milestone payments of up to \$7,000,000 upon the achievement of certain regulatory, launch and sales milestones plus double-digit percentage royalty payments on net sales.

Rheumatoid arthritis is a treatment market forecast to reach \$34.6 billion by 2020.

Psoriasis: In April 2018, Can-Fite published a paper titled "Inhibition of IL-17 and IL-23 in Human Keratinocytes by the A3 Adenosine Receptor Agonist Piclidenoson" (<https://www.hindawi.com/journals/jir/aip/2310970/>) in the Journal of Immunology Research. The Company has completed the preparatory work for its COMFORT Phase III Psoriasis study, designed to evaluate the efficacy and safety of daily Piclidenoson, administered orally compared to Apremilast (Otezla®) and placebo in around 400 patients with moderate-to-severe plaque psoriasis. The study will be conducted in 5 countries in Europe, Israel and Canada. The study protocol has been already submitted and approved by the IRB in Israel, which will be the first country to initiate enrollment.

The psoriasis therapeutic market is estimated to reach \$11.4B in 2020 according to Visiongain.

- **Namodenoson (CF102) – Can-Fite global Phase II advanced liver cancer study is fully enrolled; Potentially favorable drug safety profile has been reported; The Company continues to follow up on patients’ overall survival**

Advanced Liver Cancer: During the fourth quarter of 2017, Can-Fite reported on the progress of its Phase II liver cancer study with Namodenoson (CF102) in the treatment of advanced hepatocellular carcinoma (HCC) indicating a potentially favorable drug safety profile. The global Phase II study is being conducted in the U.S., Europe and Israel. Patients with advanced HCC, Child-Pugh Class B, who failed Nexavar (sorafenib) as a first-line treatment are treated twice daily with 25 mg of oral Namodenoson or placebo using a 2:1 randomization. The primary endpoint of the Phase II study is overall survival (OS). Secondary endpoints include progression free survival (PFS), safety, and the relationship between outcomes and A3 adenosine receptor expression. The Company anticipates data release to occur in 2H2018.

According to Datamonitor, the HCC market is expected to generate \$1.4 billion in sales in 2019.

NAFLD/NASH:

Phase II clinical study - The Company is currently conducting a Phase II trial with its drug candidate Namodenoson for the treatment of 60 patients with nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). There is currently no U.S. FDA-approved drug for the treatment of NASH, which is an addressable pharmaceutical market estimated to reach \$35-40 billion by 2025.

New pre-clinical data - In February 2018, Can-Fite announced new preclinical data supporting a novel anti-NASH mechanism of action for Namodenoson. Preclinical studies were conducted in hepato-stellate cells *in vitro* and in an experimental NASH CCL4 model, showing that in both systems, the molecular mechanism of action of Namodenoson is conferred by decreased expression levels of the signaling protein phosphoinositol-3-phosphate (PI3K) which confers three downstream signal transduction pathways, the Wnt, NF-kB and α -SMA, altogether, controlling liver inflammation, fibrosis and steatosis. The data were presented at the European Association for the Study of the Liver (EASL) annual conference.

“We continue to build positive momentum with our drug candidates. We also secured a significant distribution agreement with Gebro Holding GmbH to distribute Piclidenoson for the treatment of rheumatoid arthritis and psoriasis in three European countries. This quarter we also submitted our annual safety summaries on both Piclidenoson and Namodenoson to regulatory authorities around the world and were pleased to note that both drug candidates continue to demonstrate a favorable safety profile in human clinical trials. We look forward to providing updates on our Phase II study on Namodenoson during the second half of the year,” stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Change in Functional and Presentation Currency

From the Company’s inception through January 1, 2018, the Company’s functional and

presentation currency was the New Israeli Shekel (NIS). Management conducted a review of the functional currency of the Company and decided to change its functional and presentation currency to the U.S. dollar from the NIS effective January 1, 2018. This change was based on an assessment by Company management that the dollar is the primary currency of the economic environment in which the Company operates. Accordingly, the functional and presentation currency of the Company in the financial results presented in this press release is the U.S. dollar.

In determining the appropriate functional currency to be used, the Company followed the guidance in International Accounting Standard (IAS) 21, which states that factors relating to sales, costs and expenses, financing activities and cash flows, as well as other potential factors, should be considered. In this regard, the Company is incurring and expects to continue to incur a majority of its expenses in U.S. dollars as a result of its expanded clinical trials. These changes, as well as the fact that the majority of the Company's available funds are in U.S. dollars, the Company's principal source of financing is the U.S. capital market, and all of the Company's budgeting is conducted solely in U.S. dollars, led to the decision to make the change in functional currency as of January 1, 2018, as indicated above.

For presentation purposes, comparative figures in the financial results have been translated into dollars on the following basis: (i) monetary assets and liabilities of the Company were translated using the current rate method, using the dollar exchange rate as of December 31, 2017, (ii) non-monetary assets and liabilities of the Company and equity were translated using historical exchange rates at the relevant transaction dates, (iii) profit and loss accounts were recorded at the exchange rate at the date of the transaction, and (iv) translation differences resulting from the change in functional currency have been reported as a component of shareholders' equity.

Revenues for the three months ended March 31, 2018 were U.S. \$0.63 million compared to revenues of U.S. \$0.07 million during the three months ended March 31, 2017. The increase in revenues for the first quarter of 2018 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 Holding GmbH.

Research and development expenses for the three months ended March 31, 2018 were U.S. \$1.31 million compared with U.S. \$1.22 million for the same period in 2017. Research and development expenses for the first quarter 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. The Company expects that the research and development expenses will increase through 2018 and beyond.

General and administrative expenses were U.S. \$0.90 million for the three months ended March 31, 2018 compared to U.S. \$0.76 million for the same period in 2017. The increase is primarily due to an increase in investor relations expenses. We expect that the annual general and administrative expenses will remain at the same level as 2017.

Financial expense, net for the three months ended March 31, 2018 aggregated U.S. \$0.13 million compared to financial income, net of U.S. \$0.17 million for the same period in 2017. The increase in financial expense, net in the first quarter of 2018 was mainly due to an

increase in interest expenses related to advance payment recognition and an increase in exchange rate differences on balances of cash and cash equivalents.

Can-Fite's net loss for the three months ended March 31, 2018 was U.S. \$1.72 million compared with a net loss of U.S. \$1.74 million for the same period in 2017. The slight difference in net loss for the first quarter of 2018 was primarily attributable to an increase in revenues, which was offset by an increase in general and administrative expenses and in financial expenses, net.

As of March 31, 2018, Can-Fite had cash and cash equivalents of U.S. \$8.31 million as compared to U.S. \$3.5 million at December 31, 2017. The increase in cash during the three months ended March 31, 2018 is due to U.S. \$4.37 million received from the issuance of shares and warrants, net of issuance expenses, and the \$2.2 million advance payment received from Gebro.

The Company's consolidated financial results for the three months ended March 31, 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)

	March 31, 2018	December 31, 2017
	Unaudited	
	USD	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	8,314	3,505
Other receivable and prepaid expenses	3,205	3,159
<u>Total current assets</u>	<u>11,519</u>	<u>6,664</u>
NON-CURRENT ASSETS:		
Lease deposits	5	5
long-term investment	927	917
Property, plant and equipment, net	24	28
<u>Total long-term assets</u>	<u>956</u>	<u>950</u>

<u>Total assets</u>	<u>12,475</u>	<u>7,614</u>
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INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

<u>March 31, 2018</u>	<u>December 31, 2017</u>
<u>Unaudited</u>	
<u>USD</u>	

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	752	427
Deferred revenues	730	330
Other accounts payable	1,065	997
<u>Total current liabilities</u>	<u>2,547</u>	<u>1,754</u>

NON-CURRENT LIABILITIES:

Deferred revenues	2,499	846
<u>Total long-term liabilities</u>	<u>2,499</u>	<u>846</u>

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	2,605	2,123
Share premium	81,416	81,104
Capital reserve from share-based payment transactions	5,646	5,547
Warrants exercisable into shares	12,408	8,815
Accumulated deficit	(94,646)	(92,575)
<u>Total equity</u>	<u>7,429</u>	<u>5,014</u>

<u>Total liabilities and equity</u>	<u>12,475</u>	<u>7,614</u>
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INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

	Three months ended March 31, 2018 2017 Unaudited USD	
Revenues	<u>632</u>	<u>68</u>
Research and development expenses	1,313	1,220
General and administrative expenses	<u>907</u>	<u>762</u>
Operating loss	<u>(1,588)</u>	<u>(1,914)</u>
Finance expenses	(139)	(31)
Finance income	<u>6</u>	<u>206</u>
Total Financial income, net	<u>(133)</u>	<u>175</u>
Net loss	<u>(1,721)</u>	<u>(1,739)</u>
Net loss attributable to:		
Equity holders of the Company	(1,721)	(1,718)
Non-controlling interests	<u>-</u>	<u>(21)</u>
	<u>(1,721)</u>	<u>(1,739)</u>
Net loss per share attributable to equity holders of the Company :		
Basic and diluted net loss per share	<u>(0.05)</u>	<u>(0.05)</u>

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 a Phase III trial for rheumatoid arthritis and is expected to enter a Phase III trial for psoriasis during 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: 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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