

May 30, 2017

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

Phase III trial for rheumatoid arthritis and Phase II trial for NAFLD/NASH to commence patient enrollment

PETACH TIKVA, Israel, May 30, 2017 /PRNewswire/ --[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 three months ended March 31, 2017 and provided clinical and corporate updates.

Clinical Development Program and Corporate Highlights Include:

- **Piclidenoson (CF101) – Phase III Trials in Rheumatoid Arthritis & Psoriasis**

Rheumatoid Arthritis: Can-Fite is ready to commence its pivotal Phase III ACRobot trial of Piclidenoson by the third quarter of 2017. Shortly following the end of the first quarter, Can-Fite's ACRobot trial received Institutional Review Board (IRB) approval to commence patient enrollment at Barzilai Medical Center in Israel, one of several planned sites in Israel, Europe and Canada. Also in May, Can-Fite announced it filed a Clinical Trial Application with Health Canada to recruit patients in Canada. Piclidenoson is being developed as a first line therapy and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis. ACRobot will enroll approximately 500 patients. The estimated cost of the entire Phase III study is approximately \$5 million. This includes the cost of global clinical research organizations that have been engaged to help conduct ACRobot. The required supply of Piclidenoson has already been manufactured and paid. Can-Fite expects that this pivotal Phase III study will serve as the first of two pivotal studies required for European Medicines Agency (EMA) drug approval.

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

Psoriasis: Can-Fite's Phase III trial for Piclidenoson in the treatment of psoriasis 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 EMA agreed with Can-Fite's final trial design. Can-Fite expects to submit its clinical protocol to Institutional Review Boards (IRBs) in the fourth quarter of 2017. Can-Fite expects that this pivotal Phase III study will serve as the first of two pivotal studies required for EMA drug approval.

The psoriasis market is forecast to be \$8.9 billion in 2018 and Otezla® sales are estimated to be \$2.35 billion by 2020.

- **Namodenoson (CF102) – Phase II NAFLD/NASH Trial to Commence; Phase II Liver Cancer Trial Nearing Completion**

Liver Cancer: Can-Fite continues to enroll and dose patients in its global Phase II study of Namodenoson in the treatment of hepatocellular carcinoma, the most common form of liver cancer. A total of approximately 78 patients are expected to be enrolled in the U.S., Europe, and Israel. Completion of patient enrollment is expected in the second quarter of 2017.

Liver cancer drugs are expected to generate \$1.4 billion in sales in 2019.

NAFLD/NASH: During the first quarter of 2017, leading IRBs in Israel including Hadassah Medical Center and Rabin Medical Center cleared Can-Fite to commence patient enrollment in its Phase II clinical trial of Namodenoson in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH). The estimated cost of the Phase II trial is under \$1 million. Namodenoson supplies are ready to be administered and the costs of supply have been paid. Patient enrollment is expected to begin by the third quarter of 2017.

New preclinical data on Namodenoson was announced by Can-Fite during the first quarter. Data show that Namodenoson prevented liver (hepatic) fibrosis progression in preclinical studies, demonstrating the drug's potential efficacy in combating NAFLD/NASH.

By 2025, the addressable pharmaceutical market for NASH is estimated to reach \$35-40 billion.

- **Raised \$5 Million in Registered Direct Offering**

During the first quarter of 2017, Can-Fite received gross proceeds of \$5 million through a registered direct offering. The Company issued 2,500,000 registered American Depositary Shares (ADSs) at a purchase price of \$2.00 per ADS. For each ADS purchased by investors, the investors received an unregistered warrant to purchase 50% of an ADS. The warrants have an exercise price of \$2.25 per ADS and are exercisable six months following the issuance date and will expire five and one-half years from the issuance date.

"We look forward to commencing patient enrolment in two important trials that we believe may have a positive impact on our company. This is especially so given the modest cost of these significant trials. Our Phase III trial of Piclidenoson will evaluate our lead drug candidate as a first line therapy for rheumatoid arthritis and replacement for the current standard of care, Methotrexate (MTX). Our estimated cost for this trial is \$5 million. The Phase II trial of Namodenoson in the treatment of NAFLD/NASH, an indication for which there is currently no FDA approved drug, will cost less than \$1 million according to our estimates," stated Can-Fite CEO Dr. Pnina Fishman.

Revenues for the three months ended March 31, 2017 were NIS 0.27 million (U.S. \$0.07 million) compared to revenues of NIS 0.21 million (U.S. \$0.06 million) during the three months ended March 31, 2016. The increase in revenues for the first quarter of 2017 was mainly due to the recognition of a portion of the NIS 1.9 million (U.S. \$0.5 million) advance payment received in December 2016 under the distribution agreement with CKD.

Research and development expenses for the three months ended March 31, 2017 were NIS

4.49 million (U.S. \$1.24) compared with NIS 4.08 million (U.S. \$1.12 million) for the parallel period in 2016. Research and developments expenses for the first quarter of 2017 comprised primarily of expenses associated with the Phase II study for Namodenoson as well as expenses for ongoing studies of Piclidenoson. The increase is primarily due to costs associated with preparations of the Piclidenoson Phase III studies in the treatment of rheumatoid arthritis and psoriasis and Namodenoson for treatment in liver cancer. We expect that the research and development expenses during 2017 will not increase, as compared to 2016 levels.

General and administrative expenses were NIS 2.82 million (U.S. \$0.78 million) for the three months ended March 31, 2017 compared to NIS 2.36 million (U.S. \$0.65 million) for the same period in 2016. The increase is primarily due to bonuses paid to employees. We expect that the annual general and administrative expenses will remain at the same level as 2016.

Financial income, net for the three months ended March 31, 2017 aggregated NIS 2.49 million (U.S. \$0.69 million) compared to financial income, net of NIS 0.44 million (U.S. \$0.12 million) for the same period in 2016. The increase in financial income, net in the first quarter of 2017 was mainly due to a decrease in the fair value of warrants that are accounted as financial liability as compared to the same period in 2016.

Can-Fite's net loss for the three months ended March 31, 2017 was NIS 4.55 million (U.S. \$1.25 million) compared with a net loss of NIS 5.79 million (U.S. \$1.59 million) for the same period in 2016. The decrease in net loss for the first quarter of 2017 was primarily attributable to an increase in financial income.

As of March 31, 2017, Can-Fite had cash and cash equivalents of NIS 35.43 million (U.S. \$9.75 million) as compared to NIS 31.2 million (U.S. \$8.59 million) at December 31, 2016. The increase in cash during the three months ended March 31, 2017 is due to NIS 16.64 million (U.S. \$4.58 million) received from the issuance of shares and warrants, net of issuance 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 March 31, 2017 (U.S. \$ 1 = NIS 3.632).

The Company's consolidated financial results for the three months ended March 31, 2017 are presented in accordance with International Financial Reporting Standards.

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: 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 autoimmune-inflammatory indications, oncology and liver diseases as well as sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is headed into Phase III trials for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug Namodenoson is in a Phase II trial for patients with liver cancer and is slated to enter another Phase II for the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to 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 hepatocellular carcinoma 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. 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, 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, including, but not limited to, the factors summarized 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.

Contact

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INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

Convenience
translation
into
U.S. dollars

	<u>March 31,</u>	<u>March 31,</u>	<u>December 31,</u>
	<u>2017</u>	<u>2017</u>	<u>2016</u>
<u>Unaudited</u>			
	<u>USD</u>	<u>NIS</u>	

ASSETS

CURRENT ASSETS:

Cash and cash equivalents

	9,754	35,426	31,203
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Other receivable and prepaid expenses

	2,413	8,762	7,664
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Total current assets

	12,167	44,188	38,867
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NON-CURRENT ASSETS:

Lease deposits

	10	37	37
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Property, plant and equipment, net

	54	197	205
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Total long-term assets

	64	234	242
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Total assets

	12,231	44,422	39,109
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INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

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

	March 31, 2017	March 31, 2017	December 31, 2016
	Unaudited		
	USD	NIS	
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables	633	2,297	4,804
Deferred revenues	293	1,066	1,237
Other accounts payable	989	3,592	3,588
<u>Total current liabilities</u>	1,915	6,955	9,629
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	3,272	11,886	10,068
Deferred revenues	1,216	4,415	4,510
<u>Total long-term liabilities</u>	4,488	16,301	14,578
CONTINGENT LIABILITIES AND COMMITMENTS			
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:			

Share capital	2,282	8,289	7,039
Share premium	94,042	341,561	332,873
Capital reserve from share-based payment transactions	5,859	21,280	20,438
Warrants exercisable into shares (series 10-12)	2,473	8,983	8,983
Treasury shares, at cost	(999)	(3,628)	(3,628)
Accumulated other comprehensive loss	(234)	(852)	(883)
Accumulated deficit	<u>(97,633)</u>	<u>(354,604)</u>	<u>(349,953)</u>
<u>Total equity attributable to equity holders of the Company</u>	<u>5,790</u>	<u>21,029</u>	<u>14,869</u>
Non-controlling interests	<u>38</u>	<u>137</u>	<u>33</u>
<u>Total equity</u>	<u>5,828</u>	<u>21,166</u>	<u>14,902</u>
<u>Total liabilities and equity</u>	<u>12,231</u>	<u>44,422</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**

	Three months ended March 31,		
	2017	2017	2016
	Unaudited		
	USD	NIS	NIS
Revenues	<u>73</u>	<u>266</u>	<u>214</u>
Research and development expenses	1,236	4,488	4,077
General and administrative expenses	<u>775</u>	<u>2,817</u>	<u>2,364</u>
Operating loss	<u>1,938</u>	<u>7,039</u>	<u>6,227</u>
Finance expenses	796	2,892	1,438
Finance income	<u>(1,481)</u>	<u>(5,377)</u>	<u>(1,878)</u>
Net loss	<u>1,253</u>	<u>4,554</u>	<u>5,787</u>
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	<u>(10)</u>	<u>(38)</u>	<u>(26)</u>
Total comprehensive loss	<u>1,243</u>	<u>4,516</u>	<u>5,761</u>

Net loss attributable to:

Equity holders of the Company

1,280	4,651	5,771
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Non-controlling interests

<u>(27)</u>	<u>(97)</u>	<u>16</u>
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<u>1,253</u>	<u>4,554</u>	<u>5,787</u>
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Total comprehensive loss attributable to:

Equity holders of the Company

1,271	4,620	5,750
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Non-controlling interests

<u>(28)</u>	<u>(104)</u>	<u>11</u>
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<u>1,243</u>	<u>4,516</u>	<u>5,761</u>
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Net loss per share attributable to equity holders of the
Company :

Basic and diluted net loss per share

<u>0.04</u>	<u>0.15</u>	<u>0.21</u>
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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/can-fite-reports-first-quarter-2017-financial-results--provides-clinical-update-300464898.html>

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