

September 1, 2017

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

- **Phase II Liver Cancer Trial for Namodenoson Successfully Completes Patient Enrollment**
- **Milestone Payment Received for Namodenoson Liver Cancer Distribution Agreement in Korea**
- **Phase II Trial to Commence in Q3 2017 for Namodenoson in the Treatment of NAFLD/NASH**
- **Phase III Trial to Commence in Q3 2017 for Piclidenoson to Replace MTX as Standard of Care First Line Therapy in Rheumatoid Arthritis**

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

Clinical Development Program and Corporate Highlights Include:

## **Namodenoson (CF102): Progress in Clinical Development and Receipt of Milestone Payment**

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

Can-Fite enrolled and randomized all 78 patients for 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.

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

In August 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.

- **Namodenoson to Commence Phase II Trial in the Treatment of NAFLD/NASH**

During the second quarter of 2017, Can-Fite conducted a successful Clinical Investigator Meeting with principal investigators, researchers, and doctors participating as clinical

investigators in the Company's Phase II trial of Namodenoson in the treatment of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). Namodenoson drug supply for the trial has been paid for and is ready to be administered to patients. The trial protocol has been approved by two leading Institutional Review Boards in Israel. Can-Fite estimates the cost of this Phase II trial to be less than \$1 million. Patient enrollment is expected to begin in the third quarter of 2017. By 2025, the addressable pharmaceutical market for NASH is estimated to reach \$35-40 billion.

- **Established Clinical Advisory Board for NASH Indication**

Can-Fite established a Clinical Advisory Board comprised of Key Opinion Leaders to provide advice and steer Namodenoson's clinical development program in the treatment of NAFLD and NASH. Board members include researchers and medical practitioners in the field of liver disease from institutions including Mount Sinai in New York, Virginia Commonwealth University School of Medicine, and Hadassah University in Israel.

### **Piclidenoson (CF101): ACRobot Phase III Trial in Rheumatoid Arthritis to Commence**

In August 2017, Can-Fite successfully concluded a cardiodynamic trial for its lead drug candidate Piclidenoson, which showed favorable safety data required by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) prior to initiation of Phase III studies.

During the second quarter of 2017, Can-Fite conducted a successful Clinical Investigator Meeting with approximately 100 rheumatologists, and their staff, who are participating as clinical investigators in the Company's global pivotal Phase III ACRobot study, which is set to commence patient enrollment in the third quarter of 2017.

ACRobot is a Phase III trial that will evaluate 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 will enroll approximately 500 patients in Europe, Canada and Israel. The estimated cost of the entire Phase III study is approximately \$5 million. Rheumatoid arthritis is a treatment market forecast to reach \$34.6 billion by 2020.

Piclidenoson is also being developed as a treatment for psoriasis. Can-Fite is preparing for an upcoming Phase III trial that 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. Can-Fite expects to submit its clinical protocol to Institutional Review Boards in the fourth quarter of 2017. The psoriasis market is forecast to be \$8.9 billion in 2018 and Otezla® sales are estimated to be \$2.35 billion by 2020.

"Completion of patient enrollment in our Phase II study is a significant advancement in the development of Namodenoson to treat liver cancer. We will evaluate results as soon as possible based on survival data. There is a clear unmet medical need for HCC patients with Child-Pugh Class B cirrhosis. Our Orphan Drug status in both the U.S. and Europe, as well as Fast Track status in the U.S. in this indication, we believe will accelerate our path towards applying for market approval for Namodenoson for liver cancer," stated Can-Fite CEO Dr. Pnina Fishman. "In the current quarter, we look forward to commencing patient enrollment in our Phase II NAFLD/NASH study for Namodenoson and our Phase III rheumatoid arthritis

study for Piclidenoson.”

## **Financial Results**

Revenues for the six months ended June 30, 2017 were NIS 0.53 million (U.S. \$0.15 million) compared to NIS 0.43 million (U.S. \$0.12 million) in the first six months of 2016. The increase in revenue 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 six months ended June 30, 2017 were NIS 8.84 million (U.S. \$2.53 million) compared with NIS 9.97 million (U.S. \$2.85 million) for the same period in 2016. Research and development expenses for the first half of 2017 comprised primarily of expenses associated with the Phase II study for Namodenoson, the preclinical study of CF602, 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 six months ended June 30, 2017.

General and administrative expenses were NIS 5.0 million (U.S. \$1.43 million) for the six months ended June 30, 2017, the same as the general and administrative expenses for the same period in 2016.

Financial income, net for the six months ended June 30, 2017 aggregated NIS 1.57 million (U.S. \$0.45 million) compared to financial income, net of NIS 3.19 million (U.S. \$0.91 million) for the same period in 2016. The decrease in financial income, net in the first half of 2017 was mainly from exchange rate differences as compared to the same period in 2016 and from issuance expenses, offset by a larger decrease in the fair value of warrants that are accounted for as financial liability as compared to the same period in 2016.

Can-Fite's net loss for the six months ended June 30, 2017 was NIS 11.72 million (U.S. \$3.35 million) compared with a net loss of NIS 11.35 million (U.S. \$3.25 million) for the same period in 2016. The slight increase in net loss for the first half of 2017 was primarily attributable to a decrease in financial income, net.

As of June 30, 2017, Can-Fite had cash and cash equivalents of NIS 23.98 million (U.S. \$6.86 million) as compared to NIS 31.2 million (U.S. \$8.92 million) at December 31, 2016. The decrease in cash during the six months ended June 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 June 30, 2017 (U.S. \$1 = NIS 3.496).

The Company's consolidated financial results for the six months ended June 30, 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 cancer, inflammatory disease and sexual dysfunction. The Company's lead drug candidate, Piclidenoson, is scheduled to enter a

Phase III trial for rheumatoid arthritis in 2017 and a Phase III trial for psoriasis in early 2018. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. Can-Fite's liver cancer drug Namodenoson is in Phase II trials for patients with liver cancer and is slated to enter Phase II 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 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 and is being prepared for an IND submission to the FDA and a Phase I trial. 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: 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		
	June 30, 2017	June 30, 2017	December 31, 2016
	Unaudited		Audited
	USD		NIS
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	6,859	23,982	31,203
Other receivable and prepaid expenses	3,345	11,694	7,664
<b>Total current assets</b>	<b>10,204</b>	<b>35,676</b>	<b>38,867</b>
<b>NON-CURRENT ASSETS:</b>			
Lease deposits	8	28	37
Property, plant and equipment, net	53	185	205
<b>Total long-term assets</b>	<b>61</b>	<b>213</b>	<b>242</b>
<b>Total assets</b>	<b>10,265</b>	<b>35,889</b>	<b>39,109</b>

**INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**  
In thousands (except for share and per share data)

Convenience  
translation into  
U.S. dollars

	June 30,	June 30,	December 31,
	2017	2017	2016
	Unaudited		Audited
	USD		NIS
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Trade payables	529	1,848	4,804
Deferred revenues	305	1,066	1,237
Other accounts payable	757	2,649	3,588
<b>Total current liabilities</b>	<b>1,591</b>	<b>5,563</b>	<b>9,629</b>
<b>NON-CURRENT LIABILITIES:</b>			
Warrants exercisable into shares	3,439	12,023	10,068
Deferred revenues	1,187	4,149	4,510
<b>Total long-term liabilities</b>	<b>4,626</b>	<b>16,172</b>	<b>14,578</b>
<b>CONTINGENT LIABILITIES AND COMMITMENTS</b>			
<b>EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:</b>			
Share capital	2,371	8,289	7,039
Share premium	97,701	341,561	332,873
Capital reserve from share-based payment transactions	6,145	21,483	20,438
Warrants exercisable into shares (series 10-12)	2,570	8,983	8,983
Treasury shares, at cost	(1,038)	(3,628)	(3,628)
Accumulated other comprehensive loss	(256)	(893)	(883)
Accumulated deficit	(103,486)	(361,785)	(349,953)
<b>Total equity attributable to equity holders of the Company</b>	<b>4,007</b>	<b>14,010</b>	<b>14,869</b>

Non-controlling interests	41	144	33
Total equity	4,048	14,154	14,902
Total liabilities and equity	10,265	35,889	39,109

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

	Convenience translation into U.S. dollars		
	Six months ended June 30,		
	2017	2017	2016
	Unaudited		
	USD	NIS	NIS
Revenues	152	533	428
Research and development expenses	2,528	8,838	9,968
General and administrative expenses	1,425	4,982	4,996
Operating loss	3,801	13,287	14,536
Finance expenses	1,070	3,740	575
Finance income	(1,519)	(5,309)	(3,761)
Net loss	3,352	11,718	11,350
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	4	13	3
Total comprehensive loss	3,356	11,731	11,353
Net loss attributable to:			
Equity holders of the Company	3,384	11,832	11,186
Non-controlling interests	(32)	(114)	164

	<u>3,352</u>	<u>11,718</u>	<u>11,350</u>
<b>Total comprehensive loss attributable to:</b>			
<b>Equity holders of the Company</b>	3,387	11,841	11,188
<b>Non-controlling interests</b>	<u>(31)</u>	<u>(111)</u>	<u>165</u>
	<u>3,356</u>	<u>11,731</u>	<u>11,353</u>
<b>Net loss per share attributable to equity holders of the Company :</b>			
<b>Basic and diluted net loss per share</b>	<u>0.10</u>	<u>0.36</u>	<u>0.40</u>

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20170901005081/en/>

Can-Fite BioPharma

Motti Farbstein

[info@canfite.com](mailto:info@canfite.com)

+972-3-9241114

Source: Can-Fite BioPharma Ltd.