

November 30, 2018



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

**Revenues for the Nine Months Ended September 30, 2018 Were \$3.5 Million Compared to \$0.7 Million for the Same Period in 2017**

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](http://www.canfite.com) (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 nine months ended September 30, 2018 and provided recent clinical development and corporate updates.

“Prolonged longevity of patients in our Namodenoson Phase II advanced liver study was reported this quarter. It is a significant highlight in our clinical trial progress and because of this development, we now expect to release top-line results during the first quarter of 2019,” said Pnina Fishman, Ph.D., CEO of Can-Fite. “This development provides further encouragement that this therapy could bring value to patients with chronic liver disease and cirrhosis with a Child Pugh B score, whose disease has progressed on sorafenib therapy.”

Dr. Fishman continued, “With the need for better treatments for autoimmune inflammatory conditions such as rheumatoid arthritis and psoriasis, as well as for liver diseases such as liver cancer and NASH, we are encouraged by the progress we are making in our ongoing clinical studies. We believe there is a significant role we can play in a market that has been searching for novel therapeutic solutions for better patient care.”

## **Recent Highlights:**

### **Namodenoson for the Treatment of Liver Diseases**

- Can-Fite announced that due to patient survival, top-line results of the Namodenoson Phase II advanced liver cancer study were expected to be released in Q1 2019. The statistical plan for this trial requires that the primary efficacy analysis occurs when no more than 3 of the original 78 patients survive.
- In anticipation of the Phase II liver cancer data release, Can-Fite brought on board Professor Joseph Llovet, a Key Opinion Leader in the field of liver diseases, founder and director of the Liver Cancer Program and full professor of medicine at the Mount Sinai School of Medicine, New York University (USA). Professor Llovet will assist in the analysis of the Phase II data that are anticipated in Q1 2019.

- Can-Fite presented a poster titled “Namodenoson Anti-Fibrogenic Effect is Mediated via De-Regulation of the Wnt/ $\beta$ -catenin Pathway,” at the Hepatic Fibrosis Conference of the American Association for the Study of Liver Diseases (AASLD) in September. The data, highlighting the anti-fibrogenic effects of Namodenoson, demonstrated significant decrease in liver fibrosis upon chronic treatment with Namodenoson in the CCL4 NAFLD/NASH model.
- Can-Fite’s CEO Dr. Pnina Fishman presented on Namodenoson at NASH Summit Europe 2018 in October. Dr. Fishman spotlighted preclinical data from three experimental animal models showing that the anti-inflammatory, anti-steatotic and anti-fibrogenic effects of Namodenoson are mediated via the Wnt/ $\beta$ -catenin pathway, highly active in the liver of NAFLD/NASH animals or individuals.
- Can-Fite CEO Dr. Pnina Fishman presented on Namodenoson at The NYC Oncology Investor Conference 2018 in October. She presented the molecular mechanism mediating the anti-cancer effects of Namodenoson and described clinical data from the Company’s earlier Phase I/II liver cancer study. In addition, she presented the status of the current Phase II study in patients with advanced hepatocellular carcinoma, Child Pugh B.

### **Piclidenoson for the Treatment of Rheumatoid Arthritis and Psoriasis**

- Phase III clinical studies for the treatment of psoriasis and rheumatoid arthritis continue to enroll patients.

### **Financial Results**

Revenues for the nine months ended September 30, 2018 were \$3.5 million compared to \$0.7 million for the same period in 2017. The increase in revenue was mainly due to the recognition of the \$2 million advance payment received in August 2018 under the distribution agreement with CMS Medical and from a portion of the \$2.2 million advance payment received in January 2018 under the distribution agreement with Gebro.

Research and development expenses for the nine months ended September 30, 2018 were \$4 million compared with \$3.5 million for the same period in 2017. Research and development expenses for the nine months of 2018 were 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 the rest of 2018 and beyond.

General and administrative expenses for the nine months ended September 30, 2018 were \$2.4 million, compared to \$2.1 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 expenses, net for the nine months ended September 30, 2018 were \$0.2 million compared to financial income, net of \$0.2 million for the same period in 2017. The

increase in financial expenses, net was mainly due to recognition of interest expenses related to implementation of revenue recognition accounting standard IFRS 15, while in the same period in 2017, financial income was mainly due to fair value revaluation of warrants which were offset by financial expenses from exchange rate differences.

Can-Fite's net loss for the nine months ended September 30, 2018 was \$3.1 million compared with a net loss of \$4.7 million for the same period in 2017. The difference in net loss was primarily attributable to an increase in revenues in 2018.

As of September 30, 2018, Can-Fite had cash and cash equivalents of \$5.7 million as compared to \$3.5 million at December 31, 2017. The increase in cash during the nine months ended September 30, 2018 is due to U.S. \$4.37 million received from the issuance of shares and warrants, net of issuance expenses, the \$2.2 million advance payment received from Gebro, and \$2 million advance payment received from CMS Medical which were offset by our operating expenses.

The Company's consolidated financial results for the nine months ended September 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)**

	<u>September 30,</u> <u>2018</u> <u>Unaudited</u>	<u>December 31,</u> <u>2017</u> <u>Audited</u>
	<u>USD</u>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,728	\$ 3,505
Other receivable and prepaid expenses	3,977	3,159
<u>Total current assets</u>	<u>9,705</u>	<u>6,664</u>
<b>NON-CURRENT ASSETS:</b>		
Lease deposits	2	5
Long-term investment	1,077	917
Property, plant and equipment, net	41	28

<u>Total long-term assets</u>	1,120	950
<u>Total assets</u>	\$ 10,825	\$ 7,614

## INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

<u>September 30, 2018</u>	<u>December 31, 2017</u>
<u>Unaudited</u>	<u>Audited</u>
<u>USD</u>	

### LIABILITIES AND SHAREHOLDERS' EQUITY

#### CURRENT LIABILITIES:

Trade payables	\$ 828	\$ 427
Deferred revenues	857	330
Other accounts payable	676	997
	<u>2,361</u>	<u>1,754</u>
<u>Total current liabilities</u>		

#### NON-CURRENT LIABILITIES:

Deferred revenues	<u>2,077</u>	<u>846</u>
<u>Total long-term liabilities</u>	<u>2,077</u>	<u>846</u>

### 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	5,767	5,547
Warrants exercisable into shares	12,408	8,815
Accumulated other comprehensive income	1,127	1,127

Accumulated deficit	<u>(97,194)</u>	<u>(93,702)</u>
<u>Total equity</u>	<u>6,387</u>	<u>5,014</u>
<u>Total liabilities and equity</u>	<u>\$ 10,825</u>	<u>\$ 7,614</u>

## **INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

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

	<b>Nine months ended September 30, 2018    2017</b>	
	<b>Unaudited</b>	
	<b>USD</b>	
Revenues	<u>\$3,531</u>	<u>\$ 704</u>
Research and development expenses	4,056	3,517
General and administrative expenses	<u>2,386</u>	<u>2,100</u>
Operating loss	<u>2,911</u>	<u>4,913</u>
Finance expenses	428	288
Finance income	<u>(197)</u>	<u>(481)</u>
Total Financial income, net	<u>231</u>	<u>(193)</u>
Loss	<u>3,142</u>	<u>4,720</u>
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	-	(388)
Total other comprehensive loss	<u>\$3,142</u>	<u>\$4,332</u>

Loss attributable to:		
Equity holders of the Company	3,142	4,638
Non-controlling interests	-	82
	<u>3,142</u>	<u>\$4,720</u>
Total comprehensive loss attributable to:		
Equity holders of the Company	3,142	4,250
Non-controlling interests	-	82
	<u>3,142</u>	<u>\$4,332</u>
Loss per share attributable to equity holders of the Company :		
Basic and diluted loss per share	<u>(0.08)</u>	<u>(0.14)</u>

### **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 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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