

# Can-Fite Reports 2018 Financial Results & Provides Clinical Update

- ***Global distribution deals signed in Europe and China, including Can-Fite's largest deal to date for up to \$74.5 M***
- ***Top-line data from Phase II Namodenoson trial in the treatment of liver cancer supports continuation into Phase III study***
- ***Top-line Data from Phase II NASH Study with Namodenoson expected in H2 2019***
- ***Patient enrollment continues in two Phase III studies for Piclidenoson in the treatment of rheumatoid arthritis and psoriasis***

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 and inflammatory diseases, today announced financial results for the year ended December 31, 2018.

Clinical Development and Corporate Highlights During 2018 Include:

- In a deal worth up to \$74.5 million, Can-Fite signed a License, Collaboration and Distribution Agreement with CMS Medical Venture Investment Limited for the commercialization of Piclidenoson in the treatment of rheumatoid arthritis and psoriasis, and Namodenoson in the treatment of advanced liver cancer and NAFLD/NASH, in China.
- In another multi-million dollar deal, Can-Fite signed a distribution deal with Gebro Holding GmbH in Spain, Switzerland, and Austria, to distribute Piclidenoson in the treatment of rheumatoid arthritis and psoriasis upon receipt of regulatory approval.
- Can-Fite raised \$5 million through a registered direct offering.
- Can-Fite recently reported top line result from its Phase II trial of Namodenoson in the treatment of advanced liver cancer. While the study did not achieve its primary end point of median overall survival in the whole population of 78 patients, it did achieve superiority in median overall survival in the largest study subpopulation of 56 patients and in secondary end points for the whole population. These data support progression into a Phase III study.
- Phase III clinical studies of Piclidenoson in the treatment of psoriasis and rheumatoid arthritis continue to enroll patients.
- Top-line Data from Phase II NASH Study with Namodenoson expected in H2 2019

"2018 marked significant achievements for Can-Fite including our largest distribution deal to date valued at up to \$74.5 million. We continued to build our intellectual property assets, presented new data at scientific conferences and saw our findings published in peer reviewed journals. We are particularly pleased to move much closer to commercialization

with both Piclidenoson, now in two Phase III studies, and Namodenoson, now completing a Phase II study,” stated Can-Fite CEO Pnina Fishman. “We just announced top line results from our Phase II Namodenoson study in advanced liver cancer which produced encouraging results to move into a Phase III, even though the primary end point was not met. We believe our drugs’ strong safety profile, combined with efficacy in a specific sub-population within each target disease indication will improve patient health and longevity.”

## **Financial Results**

Revenues for the year ended December 31, 2018 were \$3.8 million, an increase of \$3.0 million, or 384%, compared to \$0.8 million for the year ended December 31, 2017. The increase in revenue was mainly due to the recognition of a \$2 million advance payment received in August 2018 under the License, Collaboration and Distribution Agreement with CMS Medical and from the recognition of a portion of the \$2.2 million advance payment received in January 2018 under the Distribution and Supply Agreement with Gebro.

Research and development expenses for the year ended December 31, 2018 were \$6.0 million, an increase of \$0.9 million, or 19%, compared to \$5.1 million for the year ended December 31, 2017. Research and developments expenses for the year ended 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 2019 and beyond.

General and administrative expenses were \$3.1 million for the year ended December 31, 2018 an increase of \$0.3 million, or 10%, compared to \$2.8 million for the year ended December 31, 2017. The increase is primarily due to an increase in professional services and investor relations expenses. We expect that general and administrative expenses will remain at the same level through 2019.

Financial expenses, net for the year ended December 31, 2018 aggregated \$1.1 million compared to immaterial financial income, net for the same period in 2017. The increase in financial expense, net was mainly due to a loss from long-term investment revaluation and from 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.

Net loss for the year ended December 31, 2018 was \$6.6 million compared with a net loss of \$6.4 million for the year ended December 31, 2017. The increase in net loss for the year ended December 31, 2018 was primarily attributable to increase in revenues in 2018 which were offset by an increase in research and development expenses and increase in finance expenses, net.

As of December 31, 2018, Can-Fite had cash and cash equivalents of \$3.6 million as compared to \$3.5 million at December 31, 2017. The increase in cash during the year ended December 31, 2018 is due to increase in net cash provided by financing activity which was offset by a decrease in net cash used in operating activity. In January 2019, Can-Fite raised \$2.35 million in a registered direct offering.

## **CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

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

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Audited</b>	
	<b>USD</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	3,615	3,505
Other receivable and prepaid expenses	4,015	3,159
Short-term investment	273	-
<b>Total current assets</b>	<b>7,903</b>	<b>6,664</b>
<b>NON-CURRENT ASSETS:</b>		
Lease deposits	2	5
long-term investment	-	917
Property, plant and equipment, net	47	28
<b>Total long-term assets</b>	<b>49</b>	<b>950</b>
<b>Total assets</b>	<b>7,952</b>	<b>7,614</b>

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

<b>December 31,</b>	
<b>2018</b>	<b>2017</b>
<b>USD</b>	

**LIABILITIES AND SHAREHOLDERS' EQUITY**

**CURRENT LIABILITIES:**

Trade payables	1,071	427
Deferred revenues	926	330
Other accounts payable	<u>1,122</u>	<u>997</u>
Total current liabilities	<u>3,119</u>	<u>1,754</u>

**NON-CURRENT LIABILITIES:**

Deferred revenues	<u>1,818</u>	<u>846</u>
Total long-term liabilities	<u>1,818</u>	<u>846</u>

**CONTINGENT LIABILITIES AND COMMITMENTS****EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:**

Share capital	2,635	2,123
Share premium	81,668	81,104
Capital reserve from share-based payment transactions	5,800	5,547
Warrants exercisable into shares	12,408	8,815
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	<u>(100,623)</u>	<u>(93,702)</u>
Total equity	<u>3,015</u>	<u>5,014</u>
Total liabilities and equity	<u><u>7,952</u></u>	<u><u>7,614</u></u>

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

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
	<b>USD</b>		
Revenues	<u>3,820</u>	<u>789</u>	<u>165</u>
Research and development expenses	6,075	5,106	6,115

General and administrative expenses	3,159	2,868	2,733
Operating loss	5,414	7,185	8,683
Other income	-	(769)	-
Finance expenses	1,204	621	55
Finance income	(51)	(633)	(374)
Total financial income, net	1,153	(12)	(319)
Loss before taxes on income	6,567	6,404	8,364
Taxes on income	4	29	29
Net loss	6,571	6,433	8,393
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	-	(636)	(119)
Total other comprehensive loss	-	(636)	(119)
Total comprehensive loss	6,571	5,797	8,274
Net loss attributable to:			
Equity holders of the Company	6,571	6,339	8,257
Non-controlling interests	-	94	136
	6,571	6,433	8,393
Total comprehensive loss attributable to:			
Equity holders of the Company	6,571	5,703	8,138
Non-controlling interests	-	94	136
	6,571	5,797	8,274
Net loss per share attributable to equity holders of the Company :			
Basic and diluted net loss per share	0.17	0.19	0.30

**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, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is in a Phase II trial 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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