

Can-Fite Reports 2017 Financial Results & Provides Clinical Update

- **A multi-million dollar agreement has been signed with Gebro Holdings for the distribution of Piclidenoson in 3 European Countries**
- **Phase III ACRobat trial of Piclidenoson in the treatment of rheumatoid arthritis currently enrolling patients**
- **Top-line data of Phase II with Namodenoson in the treatment of hepatocellular carcinoma (HCC) expected later in 2018**
- **Top-line Data from Phase II NASH Study with Namodenoson expected in H1 2019**

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 announced it has filed its 2017 Annual Report on Form 20-F with the U.S. Securities and Exchange Commission.

Clinical Development Program and Corporate Highlights Include:

Piclidenoson (CF101)

A multi-million dollar agreement has been signed with Gebro Holdings for the distribution of piclidenoson in 3 European Countries

Under the terms of the distribution agreement, Gebro made a total upfront and milestone payment of approximately \$2,200,000 to Can-Fite. In addition, the agreement provides that additional payments of up to approximately \$7,000,000 will be received by Can-Fite upon the achievement of certain regulatory, launch and sales milestones plus double-digit percentage royalty payments on net sales.

Patient enrolment for the ACRobat Phase III Trial in Rheumatoid Arthritis is ongoing

During the fourth quarter of 2017, Can-Fite commenced enrollment in the pivotal Phase III ACRobat trial of approximately 500 patients through clinical sites in Europe, Israel and Canada. The study aims to evaluate Piclidenoson (CF101) as a first line treatment and replacement for the current standard of care, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis. The primary endpoint of ACRobat is low disease activity after 12 weeks of treatment in patients dosed with Piclidenoson compared to those dosed with MTX. Piclidenoson at 1 mg and 2 mg, or placebo, will be administered twice daily, and MTX or placebo will be administered once weekly. The total study duration will be 24 weeks.

The rheumatoid arthritis market is forecast to reach \$34.6 billion by 2020.

A patent for Psoriasis has been approved in Korea

The Korean Intellectual Property Office issued patent No. 10-1741281 titled, “Pharmaceutical Composition Comprising A3 Adenosine Receptor Agonist (IB-MECA/CF-101) For Treatment of Psoriasis” for the Company’s lead drug candidate Piclidenoson in its psoriasis indication. Can-Fite has two distribution agreements in Korea, including one with Kwang Dong Pharmaceutical for Piclidenoson in the treatment of rheumatoid arthritis and another with Chong Kun Dang for Namodenoson in the treatment of liver cancer.

Namodenoson (CF102)

Progress of the Phase II Liver Cancer Namodenoson (CF102) Study in the treatment of advanced HCC – Data to be released H2/2018

Current data indicate 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 B, who failed Nexavar (sorafenib) as a first line treatment are being 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 A3AR expression. A total of approximately 78 patients have been enrolled in the Phase II study. As of December 2017, 15 subjects have completed at least 12 cycles of treatment (each cycle is 28 days of treatment), of which two completed 24 cycles. The Company anticipates data release to occur in 2H 2018.

The market for hepatocellular carcinoma drugs is expected to generate \$1.4 billion in sales in 2019.

Phase II NAFLD/NASH Study is enrolling patients; Data Release Expected in H1 2019

Can-Fite is currently enrolling patients in a Phase II study in the treatment of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) with Namodenoson which plans to enroll 60 patients. Can-Fite’s 12-week study is being led by key opinion leaders in the area of NASH and liver diseases. Clinical trial sites are some of the most prestigious medical institutions in Israel, including Hadassah Medical Center and Rabin Medical Center. Patients are being enrolled in three arms, including two different dosages of oral Namodenoson twice daily versus placebo. The study’s primary endpoints are the mean percent change from baseline in serum alanine aminotransferase (ALT) levels and safety. The secondary endpoint is percent change from baseline in hepatic steatosis measured by magnetic resonance imaging-determined by proton-density fat-fraction (MRI-PDFF) and additional metabolic parameters.

The Phase II trial design was based on preclinical studies showing Namodenoson’s efficacy in reducing liver steatosis, inflammation and fibrosis in experimental NASH models.

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.

“We’ve made several notable accomplishments during this past year which validate the strength of our drug portfolio and demonstrate our commitment in execution. We believe these events position us well for the year ahead in which we anticipate a marked progress with our Piclidenoson and Namodenoson drug candidates. We are pleased with the progress

thus far and recently announced the submission of safety reports for Piclidenoson and Namodenoson to the FDA and other regulatory authorities so that we may continue with the various clinical studies. Our drug candidates are highly unique due to our favorable safety profile and the specific anti-inflammatory and anti-cancer effects. In the coming year 2018, we remain focused on execution with the goal of providing our patients a better alternative option and treatment for autoimmune inflammatory, oncology and NASH/NAFLD,” stated Can-Fite CEO Dr. Pnina Fishman.

Financial Results

Revenues for the year ended December 31, 2017 were NIS 2.9 million (U.S. \$0.85 million), an increase of NIS 2.3 million (U.S. \$0.66 million), or 350%, compared to NIS 0.65 million (U.S. \$0.2 million) for the year ended December 31, 2016. The revenues during 2017 were mainly due to a portion of the NIS 0.76 million (U.S. \$0.22 million or CAD 0.2 million) advance payment received in March 2015 under the distribution agreement with Cipher and from the recognition of the milestone payment of NIS 1.8 million (U.S. \$0.5 million) and the recognition of a portion of the NIS 0.4 million (U.S. \$0.1 million) advance payment received in December 2016 under the distribution agreement with CKD.

Research and development expenses for the year ended December 31, 2017 were NIS 18.3 million (U.S. \$5.28 million), a decrease of NIS 5 million (U.S. 1.44 million), or 22%, compared to NIS 23.4 million (U.S. \$6.74 million) for the year ended December 31, 2016. Research and developments expenses for the year ended 2017 comprised primarily of expenses associated with the Phase II studies for Namodenoson as well as expenses for ongoing studies of Piclidenoson. The decrease is primarily due to costs associated with CF602 expenses that decreased since the postponement of a planned IND submission for this indication and decreased costs associated with the ongoing clinical trial of Namodenoson for treatment in liver cancer. The Company expects that the research and development expenses will increase through 2018 and beyond.

General and administrative expenses were NIS 10.2 million (U.S. \$2.94 million) for the year ended December 31, 2017 a decrease of NIS 0.2 million (U.S. \$0.06 million), or 2%, compared to NIS 10.5 million (U.S. \$3.02 million) for the year ended December 31, 2016. The minor decrease is primarily due to a decrease in investor and public relations expenses. The Company expects that general and administrative expenses will remain at the same level through 2018.

Financial income, net for the year ended December 31, 2017 aggregated NIS 6.6 million (U.S. \$1.89 million) compared to financial income, net of NIS 6.31 million (U.S. \$1.82 million) for the same period in 2016. The slight increase in financial income, net in the year ended December 31, 2017 was mainly due to issuance expenses recorded in 2017 which were not recorded in 2016, a decrease in net change in fair value of warrants exercisable into shares and a decrease in exchange rate difference expenses.

Can-Fite's net loss for the year ended December 31, 2017 was NIS 17.3 million (U.S. \$4.99 million) compared with a net loss of NIS 27 million (U.S. \$7.78 million) for the year ended December 31, 2016. The decrease in net loss for the year ended December 31, 2017 was primarily attributable to a decrease in research and development expenses.

As of December 31, 2017, Can-Fite had cash and cash equivalents of NIS 12.1 million (U.S.

\$3.51 million) as compared to NIS 31.2 million (U.S. \$8.99 million) at December 31, 2016. The decrease in cash during the year ended December 31, 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 December 31, 2017 (U.S. \$1 = NIS 3.467).

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

The 2017 Annual Report can be found on the Company's website at www.canfite.com as well as on the SEC website at www.sec.gov. In addition, security holders may request a hard copy of the Annual Report, which includes the Company's complete audited financial statements, free of charge. Requests can be made by contacting Can-Fite Investor Relations at 10 Bareket Street, Kiryat Matalon, Petah-Tikva 4951778, Israel or by phone at +972-3-9241114.

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 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: 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.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

Convenience translation into U.S. dollars		
December 31,	December 31,	December 31,
2017	2017	2016
Audited		
USD	NIS	

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	3,506	12,154	31,203
Other receivable and prepaid expenses	3,378	11,711	7,664

Total current assets	6,884	23,865	38,867
NON-CURRENT ASSETS:			
Lease deposits	5	18	37
long-term investment	917	3,179	-
Property, plant and equipment, net	46	160	205
Total long-term assets	968	3,357	242
Total assets	7,852	27,222	39,109

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	Convenience translation into U.S. dollars	December 31, 2017	December 31, 2017	December 31, 2016
		Audited		
	USD		NIS	
LIABILITIES AND SHAREHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Trade payables	427	1,479	4,804	
Deferred revenues	374	1,299	1,237	
Other accounts payable	1,001	3,469	3,588	
Total current liabilities	1,802	6,247	9,629	
NON-CURRENT LIABILITIES:				
Warrants exercisable into shares	2,030	7,037	10,068	
Deferred revenues	959	3,324	4,510	
Total long-term liabilities	2,989	10,361	14,578	

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	2,401	8,324	7,039
Share premium	100,283	347,684	332,873
Capital reserve from share-based payment transactions	6,296	21,828	20,438
Warrants exercisable into shares (series 10-12)	-	-	8,983
Treasury shares, at cost	-	-	(3,628)
Accumulated other comprehensive loss	-	-	(883)
Accumulated deficit	(105,919)	(367,222)	(349,953)
Total equity attributable to equity holders of the Company	3,061	10,614	14,869
Non-controlling interests	-	-	33
Total equity	3,061	10,614	14,902
Total liabilities and equity	7,852	27,222	39,109

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

	Convenience translation into U.S. dollars			
	Year ended December 31,			
	2017	2017	2016	2015
	Audited			
	USD	NIS	NIS	NIS
Revenues	847	2,936	652	643
Research and development expenses	5,285	18,322	23,380	15,052
General and administrative expenses	2,956	10,249	10,483	10,633
Operating loss	7,394	25,635	33,211	25,042

Other income	(534)	(1,853)	-	-
Finance expenses	1,102	3,822	685	2,203
Finance income	(2,999)	(10,397)	(6,999)	(7,492)
Total financial income, net	(1,897)	(6,575)	(6,314)	(5,289)
Loss before taxes on income	4,963	17,207	26,897	19,753
Taxes on income	30	104	112	17
Net loss	4,993	17,311	27,009	19,770
Other comprehensive loss:				
Total components that will be or that have been reclassified to profit or loss:				
Adjustments arising from translating financial statements of foreign operations	27	95	33	1
Remeasurement loss from defined benefit plans	-	-	-	385
Total other comprehensive	27	95	33	386
Total comprehensive loss	5,020	17,406	27,042	20,156
Net loss attributable to:				
Equity holders of the Company	4,981	17,269	26,532	18,726
Non-controlling interests	12	42	477	1,044
	4,993	17,311	27,009	19,770
Total comprehensive loss attributable to:				
Equity holders of the Company	5,015	17,388	26,559	19,112
Non-controlling interests	5	18	483	1,044
	5,020	17,406	27,042	20,156
Net loss per share attributable to equity holders of the Company :				
Basic and diluted net loss per share	0.15	0.53	0.96	0.81

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