

March 31, 2017

Can-Fite Reports 2016 Financial Results & Provides Clinical Update

-Phase III trial of Piclidenoson in the treatment of rheumatoid arthritis expected to commence in the coming months

-Safety profile of Piclidenoson well suited to meet market need for long-term treatment of auto-immune diseases without harmful side effects

PETACH TIKVA, Israel, March 31, 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 announced it has filed its 2016 Annual Report on Form 20-F with the U.S. Securities and Exchange Commission.

Clinical Development Program and Corporate Highlights Include:

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

Rheumatoid Arthritis: Can-Fite expects to be ready to commence its pivotal Phase III ACRobot trial of Piclidenoson in the second quarter of 2017. Piclidenoson is being developed as a first line therapy and replacement for the current gold standard, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis. ACRobot will enroll approximately 500 patients in Europe, Canada and Israel. 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.

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

Psoriasis: During the fourth quarter of 2016 Can-Fite reached an agreement with the European Medicines Agency (EMA) on the final design of a global pivotal Phase III trial for Piclidenoson in the treatment of psoriasis. The Phase III trial 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 (IRBs) 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.

- **Namodenoson (CF102) – Phase II NAFLD/NASH Trial to Commence; Phase II Liver Cancer Trial Nearing Completion; Upfront Payment Received in \$3 million-Plus-Royalties Distribution Deal in South Korea**

Can-Fite signed a distribution agreement with Chong Kun Dang Pharmaceuticals (CKD) for the exclusive right to distribute Namodenoson for the treatment of liver cancer in South Korea during the fourth quarter of 2016. Can-Fite has received a \$500,000 upfront payment from CKD as part of its agreement valued at up to \$3,000,000 in upfront and milestone payments. Can-Fite is entitled to 23% royalties on net sales following regulatory approval of Namodenoson in South Korea. CKD also negotiated a right of first refusal to distribute Namodenoson for other indications for which Can-Fite develops Namodenoson.

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: Leading IRBs in Israel 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), in January 2017. This approval came shortly following Can-Fite's submission of the Phase II protocol in the fourth quarter of 2016 to IRBs, including Hadassah Medical Center and Rabin Medical Center, which are expected to participate in the planned study by enrolling and treating patients. Patient enrollment is expected to begin in the second quarter of 2017.

During the fourth quarter of 2016, Can-Fite announced new preclinical data showing Namodenoson inhibited, in a dose dependent manner, the growth and proliferation of liver fibrosis cells. This suggests Namodenoson has an anti-fibrotic effect and provides further support for the drug's development as an agent to combat NAFLD.

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

- **CF602 – Patent Estate Expanded in Sexual Dysfunction**

The U.S. Patent and Trademark Office issued to Can-Fite a patent during the fourth quarter of 2016 covering A3 adenosine receptor (A3AR) ligands for use in the treatment of erectile dysfunction. The patent addresses methods for treating erectile dysfunction with different A3AR ligands including Can-Fite's erectile dysfunction drug candidate, CF602. With this new broader patent protection, Can-Fite has made a strategic decision to investigate additional compounds, owned by the Company, for the most effective and safest profile in this indication. As such, the Company postponed its planned Investigational New Drug (IND) submission for this indication.

"In the coming months, we are eager to advance our two Phase III trials for Piclidenoson in rheumatoid arthritis and psoriasis, both indications in which there is a dearth of safe and effective drugs that can be used in the long-term treatment of these auto-immune diseases. With our Phase II liver cancer trial for Namodenoson nearing completion, we are ready to start enrolling patients in our Phase II study of Namodenoson in the treatment of NAFLD/NASH. Both Piclidenoson and Namodenoson are strong candidates for partnering and distribution deals in various geographic markets," stated Can-Fite CEO Dr. Pnina Fishman.

Revenues for the twelve months ended December 31, 2016 were NIS 0.65 million (U.S. \$0.17 million) compared to revenues of NIS 0.64 million (U.S. \$0.17 million) during the year ended December 31, 2015. The revenues during 2016 were mainly due to the recognition of a portion of the NIS 5.14 million (CAD 1.65 million) advance payment received in March 2015 under the distribution agreement with Cipher and a small amount 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 twelve months ended December 31, 2016 were NIS 23.38 million (U.S. \$6.08 million) compared with NIS 15.05 million (U.S. \$3.91 million) for the same period in 2015. Research and development expenses for the year ended 2016 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 costs associated with the ongoing clinical trial of Namodenoson for treatment of liver cancer. We expect that research and development expenses will increase through 2017 and beyond.

General and administrative expenses were NIS 10.48 million (U.S. \$2.73 million) for the twelve months ended December 31, 2016 compared to NIS 10.63 million (U.S. \$2.76 million) for the same period in 2015. The minor decrease is primarily due to a decrease in professional services. We expect that general and administrative expenses will remain at the same level through 2017.

Financial income, net for the twelve months ended December 31, 2016 aggregated NIS 6.31 million (U.S. \$1.64 million) compared to financial income, net of NIS 5.29 million (U.S. \$1.38 million) for the same period in 2015. The increase in financial income, net in the year ended December 31, 2016 was mainly due to the fact that during 2016 we did not record any share issuance expenses unlike in 2015.

Can-Fite's net loss for the twelve months ended December 31, 2016 was NIS 27.01 million (U.S. \$7.02 million) compared with a net loss of NIS 19.77 million (U.S. \$5.14 million) for the same period in 2015. The increase in net loss for 2016 was primarily attributable to an increase in research and development expenses.

As of December 31, 2016, Can-Fite had cash and cash equivalents of NIS 31.2 million (U.S. \$8.12 million) as compared to NIS 66.03 million (U.S. \$17.17 million) at December 31, 2015. In addition, in January of 2017, Can-Fite raised U.S. \$5 million in a registered direct offering. The decrease in cash during the twelve months ended December 31, 2016 is mainly due to an increase in research and development 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, 2016 (U.S. \$ 1 = NIS 3.845).

The Company's consolidated financial results for the twelve months ended December 31, 2016 are presented in accordance with International Financial Reporting Standards.

The 2016 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 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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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	December 31,		
	2016	2016	2015
	USD	NIS	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	8,115	31,203	66,026
Other accounts receivable and prepaid expenses	1,993	7,664	2,419
<u>Total</u> current assets	<u>10,108</u>	<u>38,867</u>	<u>68,445</u>
NON-CURRENT ASSETS:			
Lease deposit	10	37	27
Property, plant and equipment, net	53	205	236
<u>Total</u> long-term assets	<u>63</u>	<u>242</u>	<u>263</u>
<u>Total</u> assets	<u>10,171</u>	<u>39,109</u>	<u>68,708</u>

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	December 31,		
	2016	2016	2015
	USD	NIS	
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables	1,249	4,804	1,803
Deferred revenues	322	1,237	857
Other accounts payable	933	3,588	4,279
<u>Total</u> current liabilities	2,504	9,629	6,939
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	2,618	10,068	16,725
Deferred revenues	1,173	4,510	3,641
Severance pay, net	-	-	630
<u>Total</u> Long-term liabilities	3,791	14,578	20,996

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital	1,831	7,039	7,030
Share premium	86,573	332,873	332,873
Capital reserve from share-based payment transactions	5,315	20,438	19,288
Warrants exercisable into shares (Series 10-12)	2,336	8,983	8,983
Treasury shares, at cost	(943)	(3,628)	(3,628)
Accumulated other comprehensive loss	(229)	(883)	(1,401)
Accumulated deficit	<u>(91,015)</u>	<u>(349,953)</u>	<u>(322,876)</u>
<u>Total</u> equity attributable to equity holders of the company	3,868	14,869	40,269
Non-controlling interests	<u>8</u>	<u>33</u>	<u>504</u>
<u>Total</u> equity	<u>3,876</u>	<u>14,902</u>	<u>40,773</u>
<u>Total</u> liabilities and equity	<u>10,171</u>	<u>39,109</u>	<u>68,708</u>

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

Year ended December 31,

	2016	2016	2015	2014
	USD	NIS		
Revenues	170	652	643	-
Research and development expenses	6,081	23,380	15,052	16,200
General and administrative expenses	2,726	10,483	10,633	11,573
Operating loss	8,637	33,211	25,042	27,773
Financial expenses	178	685	2,203	1,228
Financial income	(1,820)	(6,999)	(7,492)	(4,500)
Loss before taxes on income	6,995	26,897	19,753	24,501
Taxes on income	29	112	17	23
Net loss	7,024	27,009	19,770	24,524
Other comprehensive loss:				
Adjustments arising from translating financial statements of foreign operations	9	33	1	939
Remeasurement loss from defined benefit plans	-	-	385	94

Total other comprehensive loss	<u>9</u>	<u>33</u>	<u>386</u>	<u>1,033</u>
Total comprehensive loss	<u>7,033</u>	<u>27,042</u>	<u>20,156</u>	<u>25,557</u>
Net loss Attributable to:				
Equity holders of the Company	6,900	26,532	18,726	23,759
Non-controlling interests	<u>124</u>	<u>477</u>	<u>1,044</u>	<u>765</u>
	<u>7,024</u>	<u>27,009</u>	<u>19,770</u>	<u>24,524</u>
Total comprehensive loss attributable to:				
Equity holders of the Company	6,907	26,559	19,112	24,623
Non-controlling interests	<u>126</u>	<u>483</u>	<u>1,044</u>	<u>934</u>
	<u>7,033</u>	<u>27,042</u>	<u>20,156</u>	<u>25,557</u>
Net loss per share attributable to equity holders of the Company:				
Basic and diluted net loss per share	<u>0.25</u>	<u>0.96</u>	<u>0.81</u>	<u>1.35</u>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/can-fite-reports-2016-financial-results--provides-clinical-update-300432356.html>

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