

May 27, 2016

Can-Fite Reports First Quarter 2016 Financial Results & Provides Clinical Pipeline Update

PETACH TIKVA, Israel, May 27, 2016 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, today reported financial results for the three months ended March 31, 2016 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

- **CF101 – Phase II Glaucoma Results Expected in June; Phase III Trials in Rheumatoid Arthritis & Psoriasis Scheduled to Commence in 2016**

In June 2016, Can-Fite plans to report data from a Phase II trial of CF101, conducted by its subsidiary OphthaliX, in the treatment of glaucoma and related syndromes of ocular hypertension.

During the first quarter of 2016, Can-Fite submitted a Phase III trial protocol for CF101 in the treatment of rheumatoid arthritis to the European Medicines Agency (EMA) and is currently expecting EMA input.

On March 7, 2016, Can-Fite presented data at the American Academy of Dermatology's 74th Annual Meeting in Washington D.C. in a poster titled, "Treatment of Plaque-type Psoriasis with Oral CF101: Data from a Phase II/III Clinical Trial." The Company plans to file a Phase III trial protocol for CF101 in the treatment of psoriasis with the EMA in the first half of 2016 and commence the study by the end of 2016.

- **CF102 – Conducting Phase II Trial in Liver Cancer & Plans to Commence Phase II Trial in NASH**

Can-Fite continues to enroll and dose patients in its global Phase II liver cancer study in the U.S., Europe, and Israel. Completion of enrollment with approximately 78 patients is expected in the second half of 2016. The Company is preparing to file its Phase II protocol for CF102 in the treatment of non-alcoholic steatohepatitis (NASH), with institutional review boards (IRBs) in the second quarter of 2016.

- **CF602 – Reports New Pre-Clinical Data & Preparing to Submit an IND to FDA for Treatment of Sexual Dysfunction**

Following the end of the first quarter, in April 2016 Can-Fite reported new data for CF602, showing a statistically significant full recovery from erectile dysfunction after one single dose treatment in a pre-clinical diabetic model.

Can-Fite plans to file an investigational new drug (IND) application with the U.S. Food and Drug Administration for a Phase I study of CF602 in the treatment of sexual dysfunction during the fourth quarter of 2016.

"During the first quarter, we made advancements in both our drugs heading into Phase III and our earlier stage indications. For CF101, we look forward to reporting data from our Phase II glaucoma trial and anticipate receiving input from the EMA on our pivotal Phase III rheumatoid arthritis trial in the coming month," stated Can-Fite CEO Dr. Pnina Fishman.

Revenues for the three months ended March 31, 2016 were NIS 0.21 million (U.S. \$0.06 million). We did not record any revenues during the three months ended March 31, 2015. The increase in revenue was due to the recognition of a portion of the NIS 5.14 million (U.S. \$1.36 million) upfront payment received in March 2015 under the distribution agreement with Cipher Pharmaceuticals.

Research and development expenses for the three months ended March 31, 2016 were NIS 4.08 million (U.S. \$1.08 million) compared with NIS 2.33 million (U.S. \$0.62 million) for the same period in 2015. Research and development expenses for the first quarter of 2016 comprised primarily of expenses associated with the Phase II study for CF102 as well as expenses for ongoing studies of CF101. The increase is primarily due to costs associated with preparations of the CF101 Phase III studies in the treatment of rheumatoid arthritis and psoriasis.

General and administrative expenses were NIS 2.36 million (U.S. \$0.63 million) for the three months ended March 31, 2016 compared to NIS 2.48 million (U.S. \$0.66 million) for the same period in 2015. The minimal decrease is primarily due to a reduction in professional services expenses.

Financial income, net for the three months ended March 31, 2016 aggregated NIS 0.44 million (U.S. \$0.12 million) compared to financial income, net of NIS 3.3 million (U.S. \$0.88 million) for the same period in 2015. The decrease in financial income, net in the first quarter of 2016 was mainly due to a smaller decrease in the fair value of warrants that are accounted as financial liability as compared to the same period in 2015. In addition, the decrease in financial income, net in the first quarter of 2016 was attributable to an increase in expenses due to exchange rate differences as compared to the same period in 2015.

Can-Fite's net loss for the three months ended March 31, 2016 was NIS 5.79 million (U.S. \$1.54 million) compared with a net loss of NIS 1.51 million (U.S. \$0.40 million) for the same period in 2015. The increase in net loss for the first quarter of 2016 was primarily attributable to an increase in research and development expenses and a decrease in financial income, net.

As of March 31, 2016, Can-Fite had cash and cash equivalents of NIS 56.61 million (U.S. \$15.03 million) as compared to NIS 66.03 million (U.S. \$17.53 million) at December 31, 2015. The decrease in cash during the three months ended March 31, 2016 is due to 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 March 31, 2016 (U.S. \$1 = NIS 3.766).

The Company's consolidated financial results for the three months ended March 31, 2016 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)

	Convenience translation into U.S. dollars		
	March 31, 2016	March 31, 2016	December 31, 2015
	Unaudited		
	USD	NIS	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	15,032	56,610	66,026
Other receivable and prepaid expenses	1,384	5,213	2,419
<u>Total current assets</u>	<u>16,416</u>	<u>61,823</u>	<u>68,445</u>
NON-CURRENT ASSETS:			
Lease deposits	7	27	27
Property, plant and equipment, net	68	254	236
<u>Total long-term assets</u>	<u>75</u>	<u>281</u>	<u>263</u>
<u>Total assets</u>	<u>16,491</u>	<u>62,104</u>	<u>68,708</u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	Convenience translation into U.S. dollars		
	March 31, 2016	March 31, 2016	December 2015

	Unaudited		
	USD		
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables	1,005	3,784	1,005
Deferred revenues	227	857	227
Other accounts payable	843	3,174	843
<u>Total current liabilities</u>	<u>2,075</u>	<u>7,815</u>	<u>2,075</u>
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	3,968	14,942	3,968
Deferred revenues	910	3,427	910
Severance pay, net	169	636	169
<u>Total long-term liabilities</u>	<u>5,047</u>	<u>19,005</u>	<u>5,047</u>
CONTINGENT LIABILITIES AND COMMITMENTS			
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:			
Share capital	1,867	7,030	1,867
Share premium	88,389	332,873	88,389
Capital reserve from share-based payment transactions	5,192	19,552	5,192
Warrants exercisable into shares (series 10-12)	2,385	8,983	2,385
Treasury shares, at cost	(964)	(3,628)	(964)
Accumulated other comprehensive loss	(366)	(1,380)	(366)
Accumulated deficit	(87,267)	(328,647)	(87,267)
<u>Total equity attributable to equity holders of the Company</u>	<u>9,236</u>	<u>34,783</u>	<u>9,236</u>
Non-controlling interests	133	501	133
<u>Total equity</u>	<u>9,369</u>	<u>35,284</u>	<u>9,369</u>
<u>Total liabilities and equity</u>	<u>16,491</u>	<u>62,104</u>	<u>16,491</u>

In thousands (except for share and per share data)

	Convenience translation into U.S. dollars	
	Three months ended March 31,	
	2016	2016
	Unaudited	
	USD	NIS
Revenues	57	214
Research and development expenses	1,083	4,077
General and administrative expenses	628	2,364
Operating loss	1,654	6,227
Finance expenses	382	1,438
Finance income	(499)	(1,878)
Net loss	1,537	5,787
Other comprehensive loss (income):		
Adjustments arising from translating financial statements of foreign operations	(7)	(26)
Total comprehensive loss	1,530	5,761
Net loss attributable to:		
Equity holders of the Company	1,533	5,771
Non-controlling interests	4	16
	1,537	5,787
Total comprehensive loss attributable to:		
Equity holders of the Company	1,527	5,750
Non-controlling interests	3	11
	1,530	5,761
Net loss per share attributable to equity holders of the Company :		
Basic and diluted net loss per share	0.06	0.21

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 CF101 drug candidate is scheduled to enter Phase III trials in

2016 for two indications, rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug CF102 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). CF102 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. CF102 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.canfite.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

Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114

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