

May 29, 2015

Can-Fite Reports First Quarter 2015 Results

PETACH TIKVA, Israel, May 29, 2015 /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, 2015 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

- ***CF101 – Finalizing Design for Next Advanced Clinical Studies***

Can-Fite completed the design of a Phase III clinical study for the treatment of patients with rheumatoid arthritis. The Phase III design is based on positive data received from the Company's completed Phase IIb study in which CF101 was administered as a monotherapy. Can-Fite plans on submitting the Phase III study protocol to Institutional Review Boards (IRBs) for approval in the fourth quarter of 2015. Can-Fite also plans to finalize the design of its next advanced psoriasis study based on the [positive data that were released recently from its further analysis](#) of its completed Phase II/III study. Study design for the advanced psoriasis trial is expected to be completed during the second half of 2015.

- ***CF102 – Enrolling and Dosing Patients in Liver Cancer Trial***

Can-Fite continues to enroll and dose patients in its global Phase II liver cancer study. Approximately 78 patients are expected to be enrolled in the trial by the end of the first half of 2016.

- ***CF602 – Conducting Pre-Clinical Program and Preparatory Work for IND Submission***

Can-Fite is developing its third drug candidate, CF602, for the indication of sexual dysfunction. The Company is continuing its pre-clinical program and preparatory work for its upcoming Investigational New Drug (IND) submission that it intends to make to the U.S. FDA.

- ***Signed Partnership with Cipher Pharmaceuticals***

During the first quarter of 2015, Can-Fite signed a distribution agreement with Canada-based Cipher Pharmaceuticals for the distribution of CF101, for the treatment of moderate to severe psoriasis and rheumatoid arthritis in the Canadian market upon receipt of regulatory approvals. Following signing of the agreement, Cipher made an upfront payment of CDN\$1.65 million to Can-Fite.

- ***Planned Acquisition of Medical Device Company by Can-Fite Subsidiary***

OphthaliX, Can-Fite's subsidiary, which develops ophthalmic indications of CF101,

signed a non-binding term sheet to acquire Israel-based Improved Vision Systems, LTD. (I.V.S.). I.V.S. develops breakthrough medical device technology to improve sight and diagnose and offer therapy for a variety of ocular diseases and eye conditions including glaucoma, age macular degeneration (AMD), diabetic retinopathy and ocular motor pathologies, addressing multi-billion dollar markets. OphthaliX continues to enroll patients in a Phase II clinical study of CF101 for glaucoma and data release is expected during the first half of 2016.

"We advanced each of our four clinical programs in a meaningful way during the first quarter and are pleased with the pace and number of studies we are pursuing in parallel for a company of our size," stated Can-Fite CEO Dr. Pnina Fishman. "Despite not achieving its primary endpoint, we are encouraged by further analysis of our completed Phase II/III psoriasis study which showed that CF101 could serve as a first-line therapy for moderate-severe psoriasis based on the higher efficacy in patients who were previously not treated with systemic therapy."

Research and development expenses for the three months ended March 31, 2015 were NIS 2.33 million (U.S. \$0.58 million) compared with NIS 3.82 million (U.S. \$0.96 million) for the same period in 2014. Research and development expenses for the first quarter of 2015 comprised primarily of expenses associated with the Phase II study for CF102 as well as expenses for ongoing studies of CF101. The decrease is primarily due to the completion of the Phase II/III psoriasis study during the first quarter of 2015.

General and administrative expenses were NIS 2.48 million (U.S. \$0.62 million) for the three months ended March 31, 2015 compared to NIS 2.94 million (U.S. \$0.74 million) for the same period in 2014. The decrease is primarily due to a reduction in salary and professional services expenses.

Financial income, net for the three months ended March 31, 2015 aggregated NIS 3.3 million (U.S. \$0.83 million) compared to NIS 0.5 million (U.S. \$0.13 million) for the same period in 2014. The increase in financial income, net in the first quarter of 2015 was mainly due to a decrease in the fair value of warrants that are accounted as a financial liability.

Can-Fite's loss for the three months ended March 31, 2015 was NIS 1.51 million (U.S. \$0.38 million) compared with a loss of NIS 6.26 million (U.S. \$1.57 million) for the same period in 2014. The decrease in net loss for the first quarter of 2015 was attributable both to an increase in finance income, net, and a decrease in operating expenses.

As of March 31, 2015, Can-Fite had cash and cash equivalents of NIS 35.68 million (U.S. \$8.96 million) as compared to NIS 36.09 million (U.S. \$9.07 million) at December 31, 2014. The slight decrease in cash during the three months ended March 31, 2015 is due to NIS 5.14 million (U.S. \$1.29 million) received from Cipher Pharmaceuticals as upfront payment for entering into the distribution agreement with Cipher offset by 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, 2015 (U.S. \$ 1 = NIS 3.98).

The Company's consolidated financial results for the three months ended March 31, 2015 are presented in accordance with International Financial Reporting Standards.

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 recently completed its Phase II/III trials for the treatment of psoriasis and the Company is preparing for a Phase III CF101 trial for rheumatoid arthritis. Can-Fite's liver cancer drug CF102 is in Phase II trials and has been granted Orphan Drug Designation 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. The Company's CF602 has shown efficacy in the treatment of erectile dysfunction. Can-Fite has initiated a full pre-clinical program for CF602 in preparation for filing an IND with the U.S. FDA in this indication. These drugs have an excellent safety profile with experience in over 1,200 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.

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CAN-FITE BIOPHARMA LTD.

In thousands (except share and per share data)

	Convenience translation Into U.S. dollars.		
	March 31, 2015 Unaudited	March 31, 2015 Unaudited	December 31, 2014 Audited
	USD	NIS	
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	8,966	35,684	36,091
Accounts receivable	900	3,581	3,417
<u>Total current assets</u>	<u>9,866</u>	<u>39,265</u>	<u>39,508</u>
NON-CURRENT ASSETS:			
Lease deposits	4	17	26
Property, plant and equipment, net	42	166	133
<u>Total long-term assets</u>	<u>46</u>	<u>183</u>	<u>159</u>
<u>Total assets</u>	<u>9,912</u>	<u>39,448</u>	<u>39,667</u>

CAN-FITE BIOPHARMA LTD.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except share and per share data)

	Convenience translation Into U.S. dollars		
	March 31, 2015 Unaudited	March 31, 2015 Unaudited	December 31, 2014 Audited
	USD	NIS	
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables	354	1,407	1,024
Deferred revenues	1,292	5,141	-
Other accounts payable	816	3,249	4,750
<u>Total current liabilities</u>	<u>2,462</u>	<u>9,797</u>	<u>5,774</u>
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	1,111	4,420	6,969
Severance pay, net	55	219	224
<u>Total long-term liabilities</u>	<u>1,166</u>	<u>4,639</u>	<u>7,193</u>

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF
THE COMPANY:

Share capital	1,367	5,441	5,441
Share premium	75,826	301,787	301,787
Capital reserve from share-based payment transactions	4,315	17,175	17,153
Warrants exercisable into shares (series 9-12)	2,425	9,652	9,652
Treasury shares at cost	(912)	(3,628)	(3,628)
Accumulated other comprehensive loss	(303)	(1,207)	(1,015)
Accumulated deficit	(76,761)	(305,509)	(304,150)
<u>Total equity attributable to equity holders of the Company</u>	<u>5,957</u>	<u>23,711</u>	<u>25,240</u>
Non-controlling interests	327	1,301	1,460
<u>Total shareholders' equity</u>	<u>6,284</u>	<u>25,012</u>	<u>26,700</u>
<u>Total liabilities and shareholders' equity</u>	<u>9,912</u>	<u>39,448</u>	<u>39,667</u>

CAN-FITE BIOPHARMA LTD.

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

In thousands (except share and per share data)

**Convenience
translation
into
U.S. dollars**

	Three months ended March 31,		
	2015	2015	2014
	Unaudited		
	USD	NIS	NIS
Research and development expenses	585	2,328	3,825
General and administrative expenses	622	2,476	2,944
Operating loss	1,207	4,804	6,769
Finance expenses	4	17	16
Finance income	(833)	(3,316)	(527)
Net loss	378	1,506	6,258
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	59	234	16
Remeasurement loss (gain) from defined benefit plans	-	-	1
Total other comprehensive loss (income)	59	234	17

Total comprehensive loss	437	1,740	6,275
Loss attributable to:			
Equity holders of the Company	341	1,359	6,026
Non-controlling interests	37	147	232
	378	1,506	6,258
Comprehensive loss attributable to:			
Equity holders of the Company	389	1,551	6,041
Non-controlling interests	48	189	234
	437	1,740	6,275
Net loss per share attributable to equity holders of the Company :			
Basic and diluted net loss per share	0.02	0.06	0.37

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