

Can-Fite Reports Financial Results for Six Months Ended June 30, 2015

Clinical development update on advancing three drug candidates through four indications

PETACH TIKVA, Israel, Aug. 27, 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 six months ended June 30, 2015 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

- ***CF101 – Favorable Psoriasis Data, New U.S. Patent, Proposed Generic Name, and Next Advanced Clinical Studies in Rheumatoid Arthritis & Psoriasis***

During the second quarter of 2015, Can-Fite reported [positive data from further analysis](#) of its completed Phase II/III study that suggests CF101 as a potential systemic therapy for patients with moderate-severe psoriasis, this despite the [study not meeting its primary endpoint](#), as previously announced during the first quarter of 2015. Based on these findings, the Company is preparing the protocol for its next advanced psoriasis trial. During the second quarter of 2015, Can-Fite also completed the design of a Phase III clinical study for the treatment of rheumatoid arthritis and plans to submit the protocol to Institutional Review Boards (IRBs) for approval in the fourth quarter of 2015. The Company is discussing the protocol and the registration plan with its EU notified body. Further, the U.S. Patent and Trademark Office granted Can-Fite a patent covering the manufacturing process for CF101 in the U.S. and the World Health Organization accepted "piclidenoson" as the proposed generic name for CF101, both important steps prior to bringing a new drug to market.

- ***CF102 – Ongoing Phase II Liver Cancer Trial & Application for Orphan Drug Status in Europe***

Can-Fite is continuing to enroll and dose patients in its global Phase II liver cancer study. Approximately 78 patients are expected to be enrolled in the trial in the U.S., Europe, and Israel by the end of the first half of 2016. Can-Fite previously received Orphan Drug Designation in the U.S. for CF102 in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

- ***CF602 – New Pre-clinical Data Supports Upcoming IND Submission for Sexual Dysfunction Drug***

As Can-Fite prepares to file an investigational new drug (IND) application with the U.S. Food and Drug Administration prior to a Phase I clinical study of CF602 in the treatment of sexual dysfunction, the Company announced new data showing efficacy in a diabetic rat preclinical study. The animals were treated twice daily with CF602 for a period of 1 and 5 days. Treated animals showed a significant response rate resulting in a 188% and 250% increase in penial intra-cavernosal pressure, respectively compared to placebo.

- ***Update on Licensing and Distribution Agreements in Canada and Japan***

During the second quarter of 2015, Can-Fite received an upfront payment of CDN\$1.7 million following its entry into a distribution agreement with Canada-based Cipher Pharmaceuticals. In addition, on August 27, 2015, Can-Fite entered into an agreement with Japan-based Seikagaku Corporation terminating its license agreement. Seikagaku informed Can-Fite that it is strategically focused on expanding its core research and development activities in the field of glyco-science. Under the license agreement, Seikagaku was granted a license for the use, development and marketing of CF101 in Japan with respect to inflammatory indications, except for ophthalmic disease indications. The termination agreement provides, among other things, that all licenses and rights granted to Seikagaku terminate and all clinical and non-clinical studies conducted by Seikagaku shall be transferred free of charge to Can-Fite. Over the life of the license, Can-Fite received an aggregate of approximately \$8 million from Seikagaku. Can-Fite recently participated in an Israeli life sciences delegation to Japan with Israel's Office of the Chief Scientist and signed Non-Disclosure Agreements with selected Japanese companies interested in licensing CF101 and CF102. The Company's agreement with Korea-based Kwang Dong remains in place.

- ***Definitive Agreement to Acquire Improved Vision System by Can-Fite Subsidiary OphthaliX***

During the second quarter of 2015, OphthaliX, Can-Fite's subsidiary, which develops ophthalmic indications of CF101, signed a definitive agreement to acquire Israel-based Improved Vision Systems, LTD. (I.V.S.). The strategic acquisition aims to combine medical devices and pharmaceutical products to address multi-billion dollar markets in treating ophthalmic diseases.

- ***Ongoing Phase II Study in Glaucoma by Can-Fite Subsidiary OphthaliX***

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 look forward to starting advanced stage trials in the coming quarters for CF101 for both the treatment of rheumatoid arthritis and psoriasis, addressing multi-billion dollar markets. Prior advanced trials for both of these indications have produced valuable data that have helped us optimize the design of the pivotal studies, which move us closer towards applying for marketing approval," stated Can-Fite CEO Dr. Pnina Fishman. "With CF102 in Phase II for liver cancer and our anticipated IND filing for CF602 in sexual dysfunction in the third quarter of 2016, we believe we are well positioned with four distinct clinical programs. During the first half of 2015, we have forged a strategic partnership in Canada and are excited about new opportunities in the Japanese market."

Research and development expenses for the six months ended June 30, 2015 were NIS 5.75 million (U.S. \$1.53 million) compared with NIS 8.64 million (U.S. \$2.29 million) for the same period in 2014. Research and developments expenses for the first half 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 psoriasis Phase II/III study during the first quarter of 2015 and a decrease in the scope of the non-clinical expenses during the first six months of 2015 compared to the same period in 2014.

General and administrative expenses were NIS 4.67 million (U.S. \$1.24 million) for the six months ended June 30, 2015 compared to NIS 5.43 million (U.S. \$1.44 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 six months ended June 30, 2015 was NIS 1.88 million (U.S. \$0.50 million) compared to NIS 1.71 million (U.S. \$0.45 million) for the same period in 2014. The increase in financial income, net in the first half of 2015 was mainly due to a decrease in the fair value of warrants that are accounted as financial liability.

Can-Fite's loss for the six months ended June 30, 2015 was NIS 8.27 million (U.S. \$2.19 million) compared with a loss of NIS 12.36 million (U.S. \$3.28 million) for the same period in 2014. The decrease in net loss for the first half of 2015 was attributable mainly to a decrease in operating expenses.

As of June 30, 2015, Can-Fite had cash and cash equivalents of NIS 29.20 million (U.S. \$7.75 million) as compared to NIS 36.09 million (U.S. \$9.58 million) at December 31, 2014. The decrease in cash during the six months ended June 30, 2015 is due to operating expenses offset by NIS 5.14 million (U.S. \$1.36 million) received from Cipher Pharmaceuticals as upfront payment for entering into the distribution agreement with Cipher.

For the convenience of the reader, the reported NIS amounts have been translated into U.S. dollars, at the representative rate of exchange on June 30, 2015 (U.S. \$ 1 = NIS 3.769).

The Company's consolidated financial statements for the six months ended June 30, 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 is preparing for a Phase III CF101 trial for rheumatoid arthritis and is preparing its protocol for its next advanced psoriasis clinical trial. 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. INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except share and per share data)

Convenience translation into U.S. dollars		
<u>June 30,</u>	<u>June 30,</u>	<u>December 31,</u>
<u>2015</u>	<u>2015</u>	<u>2014</u>
<u>Unaudited</u>	<u>Unaudited</u>	<u>Audited</u>
NIS		
<u>USD</u>		

ASSETS

CURRENT ASSETS:

Cash and cash equivalents

7,747

29,199

36,091

Accounts receivable and prepaid expenses	758	2,856	
			3,417
<u>Total current assets</u>	8,505	32,055	39,508
NON-CURRENT ASSETS:			
Lease deposits	7	26	26
Property, plant and equipment, net	65	246	133
<u>Total long-term assets</u>	72	272	159
<u>Total assets</u>	8,577	32,327	39,667

**CAN-FITE BIOPHARMA LTD.
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

In thousands (except share and per share data)

Convenience translation into U.S. dollars		
June 30,	June 30,	December 31,
2015	2015	2014
Unaudited	Unaudited	Audited
NIS		
USD		

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	356	1,342	1,024
Deferred revenues	287	1,082	-
Other accounts payable	763	2,876	4,750
<u>Total current liabilities</u>	<u>1,406</u>	<u>5,300</u>	<u>5,774</u>

NON-CURRENT LIABILITIES:

Warrants exercisable into shares	1,087	4,097	6,969
Deferred revenues	1,005	3,788	-
Severance pay, net	57	214	224
<u>Total long-term liabilities</u>	<u>2,149</u>	<u>8,099</u>	<u>7,193</u>

COMMITMENTS AND CONTINGENT LIABILITIES

SHAREHOLDERS' EQUITY

Share capital	1,444	5,441	5,441
Share premium	80,248	302,456	301,787
Capital reserve from share-based payment transactions	4,570	17,225	17,153

Warrants exercisable into shares (series 9-12)	2,384	8,983	9,652
Treasury shares	(963)	(3,628)	(3,628)
Accumulated other comprehensive loss	(189)	(711)	(1,015)
Accumulated deficit	(82,794)	(312,048)	(304,150)
<u>Equity attributable to equity holders of the Company</u>	<u>4,700</u>	<u>17,718</u>	<u>25,240</u>
Non-controlling interests	321	1,210	1,460
<u>Total shareholders' equity</u>	<u>5,021</u>	<u>18,928</u>	<u>26,700</u>
<u>Total liabilities and shareholders' equity</u>	<u>8,577</u>	<u>32,327</u>	<u>39,667</u>

**CAN-FITE BIOPHARMA LTD.
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

In thousands (except share and per share data)

Convenience translation into U.S. dollars		
Six months ended June 30,		
2015	2015	2014
Unaudited		
USD	NIS	NIS

Revenues	72	271	-
Research and development expenses	1,526	5,751	8,636
General and administrative expenses	<u>1,239</u>	<u>4,670</u>	<u>5,425</u>
Operating loss	<u>2,693</u>	<u>10,150</u>	<u>14,061</u>
Finance expenses	267	1,005	780
Finance income	<u>(766)</u>	<u>(2,886)</u>	<u>(2,485)</u>
Net loss	<u>2,194</u>	<u>8,269</u>	<u>12,356</u>
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	<u>(98)</u>	<u>(370)</u>	<u>(65)</u>
Total comprehensive loss	<u>2,096</u>	<u>7,899</u>	<u>12,291</u>
Loss attributable to:			
Equity holders of the Company	2,095	7,898	12,014
Non-controlling interests	<u>99</u>	<u>371</u>	<u>342</u>
	<u>2,194</u>	<u>8,269</u>	<u>12,356</u>

Comprehensive loss attributable to:

Equity holders of the Company

2,015	7,594	11,962
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Non-controlling interests

81	305	329
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2,096	7,899	12,291
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Net loss per share attributable to equity holders of the Company :

Basic and diluted net loss per share

0.09	0.37	0.71
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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/can-fite-reports-financial-results-for-six-months-ended-june-30-2015-300134464.html>

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