

August 26, 2016

Can-Fite Reports Financial Results for Six Months Ended June 30, 2016

Clinical update on treatments for rheumatoid arthritis, psoriasis, liver cancer, NASH and sexual dysfunction

PETACH TIKVA, Israel, Aug. 26, 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 six months ended June 30, 2016 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

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

Rheumatoid Arthritis: Can-Fite reached an agreement with the European Medicine Agency (EMA) on the protocol design of its upcoming Phase III trial of Piclidenoson in the treatment of rheumatoid arthritis. Based on the suggestion of the EMA, Piclidenoson will be developed as a first line therapy and replacement for the current gold standard, Methotrexate (MTX), the most widely used drug for rheumatoid arthritis, a treatment market forecast to reach \$38.5 billion by 2017. The planned Phase III trial will aim to show Piclidenoson is not inferior to MTX. Based on this clinical study design, Can-Fite is now conducting preparatory work for the trial including drug tableting, packaging and labeling work. The Company plans to submit its study protocol to the Institutional Review Boards (IRBs) of clinical sites in the first quarter of 2017.

Psoriasis: Can-Fite submitted a Phase III clinical trial protocol for Piclidenoson in the treatment of moderate-to-severe psoriasis with the EMA in the first half of 2016. Based on a pre-submission meeting the Company had with the EMA, the planned trial will be a head-to-head study comparing Piclidenoson to apremilast (Otezla®), a recently approved oral drug from Celgene. Can-Fite expects a meeting with the EMA to discuss the trial's design in the third quarter of 2016.

New mechanism of action data showing Piclidenoson may offer efficacy similar to industry-leading biologics, without the associated harmful side effects, were presented by Can-Fite at Psoriasis 2016, the 5th Congress of the Psoriasis International Network, in Paris, France. The oral presentation titled, "CF101 via A3AR Activation inhibits IL-17 and IL-23," was delivered on July 7, 2016.

The peer reviewed scientific journal, *Journal of Drugs in Dermatology*, published data from a Phase II/III trial of Piclidenoson in the treatment of moderate to severe psoriasis. The study titled, "Treatment of Plaque-Type Psoriasis With Oral CF101: Data from a Phase II/III Multicenter, Randomized, Controlled Trial," was published in August 2016.

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

Liver Cancer: Can-Fite continues to enroll and dose patients in its global Phase II study of CF102 in the treatment of hepatocellular carcinoma, the most common form of liver cancer. Enrollment of approximately 78 patients in the U.S., Europe, and Israel is expected to conclude in the second half of 2016.

NASH: Can-Fite worked with world renowned Key Opinion Leaders in the field of liver diseases to complete the protocol design for its upcoming Phase II trial of CF102 in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH). By 2025, the addressable pharmaceutical market for NASH is estimated to reach \$35-40 billion. The Company plans to file its protocol with IRBs in the second half of 2016.

- **CF602 – Preparing for Phase I in the Treatment of Sexual Dysfunction**

Can-Fite is currently conducting Investigational New Drug (IND) enabling studies of CF602 in the treatment of sexual dysfunction to support commencing a Phase I study in the first quarter of 2017. The Company presented data at the American Urology Association's Annual 2016 Meeting in San Diego, California. The presentation titled, "CF602 Improves Erectile Dysfunction in Diabetic Rats," was delivered on May 10, 2016. CF602's mechanism of action, its efficacy in increasing penile intracavernous pressure (ICP), and single dose efficacy were included in the presentation.

"In the first half of 2016, we were particularly encouraged by feedback received from the EMA, indicating we conduct head-to-head studies of Piclidenoson in psoriasis and rheumatoid arthritis. These studies will compare Piclidenoson to drugs that are used as the standard of care today. Because of Piclidenoson's well established safety profile, proving efficacy that is equivalent to the comparative drugs would highlight the benefits of Piclidenoson in delivering a safe, effective and oral treatment," stated Can-Fite CEO Dr. Pnina Fishman. "In addition to heading into Phase III studies of Piclidenoson, we are pleased to continue the development programs of CF102 and CF602 to address unmet clinical needs."

Revenues for the six months ended June 30, 2016 were NIS 0.43 million (U.S. \$0.11 million) compared to NIS 0.27 million (U.S. \$0.07 million) in the first six months of 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 six months ended June 30, 2016 were NIS 9.97 million (U.S. \$2.59 million) compared with NIS 5.75 million (U.S. \$1.5 million) for the same period in 2015. Research and development expenses for the first half of 2016 comprised primarily of expenses associated with the Phase II study for CF102, preclinical study for CF602, 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 4.99 million (U.S. \$1.3 million) for the six

months ended June 30, 2016 compared to NIS 4.67 million (U.S. \$1.21 million) for the same period in 2015. The increase is primarily due to an increase in share based compensation expense.

Financial income, net for the six months ended June 30, 2016 aggregated NIS 3.19 million (U.S. \$0.83 million) compared to financial income, net of NIS 1.88 million (U.S. \$0.49 million) for the same period in 2015. The increase in financial income, net in the first half of 2016 was mainly due to a larger decrease in the fair value of warrants that are accounted for as financial liability as compared to the same period in 2015. In addition, the increase in financial income, net in the first half of 2016 was attributable to a decrease in financial expenses due to exchange rate differences as compared to the same period in 2015.

Can-Fite's net loss for the six months ended June 30, 2016 was NIS 11.35 million (U.S. \$2.95 million) compared with a net loss of NIS 8.27 million (U.S. \$2.15 million) for the same period in 2015. The increase in net loss for the first half of 2016 was primarily attributable to an increase in research and development expenses offset by an increase in financial income, net.

As of June 30, 2016, Can-Fite had cash and cash equivalents of NIS 46.42 million (U.S. \$12.07 million) as compared to NIS 66.03 million (U.S. \$17.17 million) at December 31, 2015. The decrease in cash during the six months ended June 30, 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 June 30, 2016 (U.S. \$1 = NIS 3.846).

The Company's consolidated financial results for the six months ended June 30, 2016 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 lead drug candidate, Piclidenoson, is scheduled to enter Phase III trials in 2016 for two indications, rheumatoid arthritis and psoriasis. The rheumatoid arthritis Phase III protocol has recently been agreed with the European Medicines Agency. 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.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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INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

Convenience translation into U.S. dollars		
June 30, 2016	June 30, 2016	December 31, 2015
Unaudited		Audited
USD		NIS

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	12,070	46,422	66,026
Other receivable and prepaid expenses	1,717	6,604	2,419
<u>Total current assets</u>	<u>13,787</u>	<u>53,026</u>	<u>68,445</u>

NON-CURRENT ASSETS:

Lease deposits	7	27	27
Property, plant and equipment, net	62	237	236
<u>Total long-term assets</u>	<u>69</u>	<u>264</u>	<u>263</u>
<u>Total assets</u>	<u>13,856</u>	<u>53,290</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

June 30,

June 30,

December 31,

	2016	2016	2015
	Unaudited		Audited
	USD	NIS	
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables	635	2,442	1,803
Deferred revenues	223	857	857
Other accounts payable	742	2,855	4,279
<u>Total current liabilities</u>	<u>1,600</u>	<u>6,154</u>	<u>6,939</u>
NON-CURRENT LIABILITIES:			
Warrants exercisable into shares	3,419	13,151	16,725
Deferred revenues	836	3,213	3,641
Severance pay, net	167	643	630
<u>Total long-term liabilities</u>	<u>4,422</u>	<u>17,007</u>	<u>20,996</u>
CONTINGENT LIABILITIES AND COMMITMENTS			
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:			

Share capital	1,830	7,039	7,030
Share premium	86,550	332,873	332,873
Capital reserve from share-based payment transactions	5,194	19,976	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	(365)	(1,403)	(1,401)
Accumulated deficit	<u>(86,859)</u>	<u>(334,062)</u>	<u>(322,876)</u>
<u>Total equity attributable to equity holders of the Company</u>	<u>7,743</u>	<u>29,778</u>	<u>40,269</u>
Non-controlling interests	<u>91</u>	<u>351</u>	<u>504</u>
<u>Total equity</u>	<u>7,834</u>	<u>30,129</u>	<u>40,773</u>
<u>Total liabilities and equity</u>	<u>13,856</u>	<u>53,290</u>	<u>68,708</u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

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

	Six months ended June 30,		
	2016	2016	2015
	Unaudited		
	USD	NIS	NIS
Revenues	111	428	271
Research and development expenses	2,592	9,968	5,751
General and administrative expenses	1,299	4,996	4,670
Operating loss	3,780	14,536	10,150
Finance expenses	149	575	1,005
Finance income	(978)	(3,761)	(2,886)
Net loss	2,951	11,350	8,269
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	1	3	(370)
Total comprehensive loss	2,952	11,353	7,899

Net loss attributable to:

Equity holders of the Company	2,908	11,186	7,898
Non-controlling interests	43	164	371
	<u>2,951</u>	<u>11,350</u>	<u>8,269</u>

Total comprehensive loss attributable to:

Equity holders of the Company	2,909	11,188	7,594
Non-controlling interests	43	165	305
	<u>2,952</u>	<u>11,353</u>	<u>7,899</u>

Net loss per share attributable to equity holders of the Company :

Basic and diluted net loss per share	0.10	0.40	0.37
Basic and diluted net loss per share	<u>0.10</u>	<u>0.40</u>	<u>0.37</u>

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-30-2016-300318054.html>

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