

November 25, 2016



Can-Fite Reports Financial Results for Nine Months Ended September 30, 2016 & Provides Clinical Update

-- \$3,000,000 distribution deal signed for Namodenoson (CF102) in South Korea

-- Piclidenoson is being developed as a first line therapy and replacement for the current gold standard, Methotrexate in the treatment of rheumatoid arthritis

-- EMA grants clearance to commence Phase III psoriasis trial for Piclidenoson

-- Phase II protocol for NAFLD/NASH submitted to IRB

PETACH TIKVA, Israel, Nov. 25, 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 nine months ended September 30, 2016 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

- **Piclidenoson (CF101) – EMA Clearance Received for Phase III Trials in Rheumatoid Arthritis & Psoriasis to Commence in 2017**

Rheumatoid Arthritis: 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. The Company plans to submit its study protocol to Institutional Review Boards (IRBs) of clinical sites in the first quarter of 2017.

Rheumatoid arthritis is a treatment market forecast to reach \$38.5 billion by 2017.

Psoriasis: 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, expected to commence enrollment in the second half of 2017, 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.

During the third quarter, Can-Fite received a Notice of Allowance from the European Patent Office indicating the patent titled, "Pharmaceutical Composition Comprising A3 Adenosine Receptor Agonist (IB-MECA/CF-101) for Treatment of Psoriasis" will be granted.

The *Journal of Drugs in Dermatology* published data in August from Can-Fite's Phase II/III trial of Piclidenoson in the treatment of moderate to severe psoriasis. The study is titled "Treatment of Plaque-Type Psoriasis With Oral CF101: Data from a Phase II/III Multicenter, Randomized, Controlled Trial."

The psoriasis market is forecast to be \$8.9 billion in 2018.

- **Namodenoson (CF102) – Distribution deal in South Korea; Ongoing Phase II in Liver Cancer & Phase II NAFLD/NASH Protocol Submitted to IRB**

In October, 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. The deal includes up to \$3,000,000 in upfront and milestone payments, plus a percentage of royalties on net sales in the low twenties. CKD also negotiated for 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.

Molecular Medicine Report published an article titled, "A3 adenosine receptor agonist, CF102, protects against hepatic ischemia/reperfusion injury following partial hepatectomy" during the third quarter. The article reports the results of preclinical studies conducted by Can-Fite, showing Namodenoson protects the liver from ischemia/reperfusion injury and regenerates liver cells following partial hepatectomy.

Liver cancer drugs are expected to generate \$1.4 billion in sales in 2019.

NAFLD/NASH: In conjunction with world renowned Key Opinion Leaders in the field of liver diseases, Can-Fite completed the study design of its upcoming Phase II trial of Namodenoson in the treatment of non-alcoholic fatty liver disease (NAFLD), the precursor to non-alcoholic steatohepatitis (NASH).

This Phase II clinical trial protocol was submitted to leading Institutional Review Boards (IRB) in Israel. Top medical centers in Israel, including Hadassah Medical Center and Rabin Medical Center are expected to participate in the planned study by enrolling and treating patients.

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

- **CF602 – Broad Patent Estate in Sexual Dysfunction & Other Indications**

A Notice of Allowance was granted to Can-Fite by the U.S. Patent and Trademark Office in November for the Company's patent application 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 will postpone its planned Investigational New Drug (IND) submission for this indication.

"Today Can-Fite stands poised to enter two pivotal Phase III trials in autoimmune disease where there is a clear need for an effective oral drug that can be taken safely, on a long-term basis. In the treatment of liver diseases, we look forward to completing our Phase II trial in liver cancer and commencing a Phase II trial in NAFLD/NASH. We believe our small molecule oral drug candidates offer very clear advantages over other drugs on the market that patients cannot tolerate longer term due to safety and IV administration issues. Along with benefits to patients, it is our strong belief that our drug candidates will improve healthcare economics and create growing value for our shareholders," stated Can-Fite CEO Dr. Pnina Fishman.

Revenues for the nine months ended September 30, 2016 were NIS 0.64 million (U.S. \$0.17 million) compared to NIS 0.54 million (U.S. \$0.14 million) in the first nine 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 nine months ended September 30, 2016 were NIS 15.45 million (U.S. \$4.11 million) compared with NIS 9.58 million (U.S. \$2.55 million) for the same period in 2015. Research and development expenses for the first nine months 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 due to costs associated with preparations of the aforementioned studies.

General and administrative expenses were NIS 7.88 million (U.S. \$2.1 million) for the nine months ended September 30, 2016 compared to NIS 6.79 million (U.S. \$1.81 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 nine months ended September 30, 2016 aggregated NIS 3.12 million (U.S. \$0.83 million) compared to financial expenses, net of NIS 4.7 million (U.S. \$1.25 million) for the same period in 2015. The increase in financial income, net in the first nine month of 2016 was mainly due to a decrease in the fair value of warrants that are accounted for as financial liability as compared to an increase in the fair value of these warrants in the same period in 2015. In addition, the increase in financial income, net in the first nine months of 2016 was offset by an increase in financial expenses due to exchange rate differences as compared to insignificant financial income from exchange rate differences and capital issuance expenses for the same period in 2015.

Can-Fite's net loss for the nine months ended September 30, 2016 was NIS 19.56 million (U.S. \$5.2 million) compared with a net loss of NIS 20.53 million (U.S. \$5.46 million) for the same period in 2015. The decrease in net loss for the first nine month of 2016 was primarily attributable to an increase in financial income, net offset by an increase in research and development expenses.

As of September 30, 2016, Can-Fite had cash and cash equivalents of NIS 37.57 million (U.S. \$10 million) as compared to NIS 66.03 million (U.S. \$17.57 million) at December 31, 2015. The decrease in cash during the nine months ended September 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 September 30, 2016 (U.S. \$1 = NIS 3.758).

The Company's consolidated financial results for the nine months ended September 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 Namodenoson 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). 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 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.

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

	Convenience translation into U.S. dollars		
	September 30, 2016	September 30, 2016	December 31, 2015
	Unaudited		Audited
	USD		NIS
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	9,997	37,571	66,026
Other receivable and prepaid expenses	1,744	6,553	2,419
<u>Total current assets</u>	<u>11,741</u>	<u>44,124</u>	<u>68,445</u>
NON-CURRENT ASSETS:			

Lease deposits	10	37	27
Property, plant and equipment, net	<u>58</u>	<u>219</u>	<u>236</u>
<u>Total long-term assets</u>	<u>68</u>	<u>256</u>	<u>263</u>
<u>Total assets</u>	<u>11,809</u>	<u>44,380</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		
	<u>September 30,</u>	<u>September 30,</u>	<u>December 31,</u>
	2016	2016	2015
	Unaudited		Audited
	USD		
	NIS		

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	600	2,254	1,803
Deferred revenues	228	857	857
Other accounts payable	<u>785</u>	<u>2,950</u>	<u>4,279</u>

Total current liabilities

1,613 6,061 6,939

NON-CURRENT LIABILITIES:

Warrants exercisable into shares

3,315 12,458 16,725

Deferred revenues

798 2,999 3,641

Severance pay, net

174 650 630

Total long-term liabilities

4,287 16,107 20,996

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

Share capital

1,873 7,039 7,030

Share premium

88,577 332,873 332,873

Capital reserve from share-based payment transactions

5,390 20,256 19,288

Warrants exercisable into shares (series 10-12)

2,390 8,983 8,983

Treasury shares, at cost

(965) (3,628) (3,628)

Accumulated other comprehensive loss

(371) (1,393) (1,401)

Accumulated deficit

(91,051) (342,170) (322,876)

Total equity attributable to equity holders of the Company

5,843 21,960 40,269

Non-controlling interests	66	252	504
<u>Total equity</u>	<u>5,909</u>	<u>22,212</u>	<u>40,773</u>
<u>Total liabilities and equity</u>	<u>11,809</u>	<u>44,380</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		
	Nine months ended September 30,		
	2016	2016	2015
	Unaudited		
	USD	NIS	NIS
Revenues	171	643	541
Research and development expenses	4,111	15,449	9,580
General and administrative expenses	2,096	7,878	6,793
Operating loss	6,036	22,684	15,832
Finance expenses	375	1,411	4,862

Finance income	<u>(1,207)</u>	<u>(4,535)</u>	<u>(167)</u>
Net loss	<u>5,204</u>	<u>19,560</u>	<u>20,527</u>
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	(3)	(10)	117
Total comprehensive loss	<u>5,201</u>	<u>19,550</u>	<u>20,644</u>
Net loss attributable to:			
Equity holders of the Company	5,134	19,294	19,911
Non-controlling interests	<u>70</u>	<u>266</u>	<u>616</u>
	<u>5,204</u>	<u>19,560</u>	<u>20,527</u>
Total comprehensive loss attributable to:			
Equity holders of the Company	5,132	19,286	20,007
Non-controlling interests	<u>69</u>	<u>264</u>	<u>637</u>
	<u>5,201</u>	<u>19,550</u>	<u>20,644</u>
Net loss per share attributable to equity holders of the Company :			
Basic and diluted net loss per share	<u>0.19</u>	<u>0.70</u>	<u>0.93</u>

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/can-fite-reports-financial-results-for-nine-months-ended-september-30-2016--provides-clinical-update-300367548.html>

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