

Can-Fite Reports Financial Results for Nine Months Ended September 30, 2015

Significant developments with CF102 in liver cancer and NASH, plus three additional indications for CF101 and CF602 in Rheumatoid Arthritis, Psoriasis and Sexual Dysfunction

PETACH TIKVA, Israel, Nov. 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 nine months ended September 30, 2015 and updates on its drug development programs.

Clinical Development Program and Corporate Highlights Include:

- ***Fortifies Balance Sheet with \$13.8 Million Fund Raise***

During September 2015, Can-Fite closed on approximately \$9 million in funding from institutional investors. As of September 30, 2015 Can-Fite had cash and cash equivalents of \$14.46 million. In October the Company raised an additional \$4.8 million.

- ***CF102 – Receives Fast Track Designation in U.S. & Orphan Drug Designation in Europe; Reports Compelling Preclinical Data and Files Patent for NASH***

During, and immediately following, the third quarter of 2015, three significant events moved CF102's clinical development forward. 1) The U.S. Food and Drug Administration (FDA) granted Fast Track Designation to CF102 as a second line treatment for hepatocellular carcinoma (HCC), the most common form of liver cancer. With [Fast Track](#) CF102 benefits from more frequent meetings and communications with the FDA to review the drug's development plan to support approval, while also allowing the Company to submit parts of the New Drug Application (NDA) on a rolling basis for review as data becomes available. CF102 also has the FDA's Orphan Drug Designation. 2) In October 2015, the European Medicines Agency (EMA) granted [Orphan Drug Designation](#) to CF102 for the indication of HCC, giving CF102 protocol assistances and a 10-year market exclusivity following market approval in 28 EU member states and 3 additional European Economic Area countries. 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 in the U.S., Europe, and Israel by June 30, 2016. 3) In November 2015, the Company reported data from a preclinical study of an animal model of non-alcoholic steatohepatitis (NASH), revealing CF102 had a statistically significant reduction in liver pathology. This data supports the development of CF102 for NASH, which represents a large and unmet medical need, with no U.S. FDA approved treatment currently available. The addressable market for the treatment of NASH in 2025 is estimated at \$35-\$40 billion by Deutsche Bank. Can-Fite filed a patent for CF102 in the treatment of NASH.

- ***CF602 – Reports Mechanism of Action Study Data for Upcoming IND Submission***

In October 2015, Can-Fite reported new findings for its CF602 drug candidate showing a defined mechanism of action in erectile dysfunction similar to sildenafil (Viagra®) in a rat model of diabetes mellitus. CF602 demonstrated effects on erection superior to that of Viagra in animal studies. Viagra, sold by Pfizer, generated global sales of \$1.685 billion in 2014. Can-Fite plans to file an Investigational New Drug (IND) application with the FDA for CF602 in the third quarter of 2016.

- **CF101 – Preparing for Phase III trials in Rheumatoid Arthritis & Psoriasis**

Can-Fite is currently preparing the protocol for its Phase III trial of CF101 in the treatment of psoriasis. Protocol design is scheduled for completion by the end of 2015. Having already completed the Phase III protocol for CF101 in the treatment of rheumatoid arthritis, Can-Fite plans to submit this protocol to Institutional Review Boards (IRBs) during in the fourth quarter of 2015. Marking an important step for CF101 prior to coming to market, "piclidenoson" was accepted as the drug's proposed generic by the World Health Organization.

- **Enrolling Patients in Ongoing Phase II Glaucoma Study 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.

"During and immediately following the third quarter, we achieved regulatory milestones for CF102 that we believe will significantly accelerate our liver cancer drug's time to market. Given the lack of effective medications for liver cancer, we are pleased that Fast Track designation in the U.S. and Orphan Drug designation in Europe are designed to expedite CF102's pathway through advanced clinical trials and into market approval. NASH, another large and unmet medical need, has just emerged as a potential new indication for CF102 based on compelling new preclinical data," stated Can-Fite CEO Dr. Pnina Fishman. "We also very encouraged by the new mechanism of action data we reported for CF602 in sexual dysfunction. These animal studies demonstrated that CF602 produced erectile effects superior to Viagra and therefore we believe it has the potential to offer value in the market. We are currently preparing CF602's IND for the indication of sexual dysfunction."

"As we look ahead to 2016, we are preparing to commence Phase III trials for CF101 in both psoriasis and rheumatoid arthritis. With a portfolio of indications that are all advancing towards market, we were pleased to fortify our balance sheet with \$13.8 million from institutional investors," Dr. Fishman added.

Research and development expenses for the nine months ended September 30, 2015 were NIS 9.58 million (U.S. \$2.44 million) compared with NIS 12.44 million (U.S. \$3.17 million) for the same period in 2014. Research and developments expenses for the nine months 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 and a decrease in the scope of the non-clinical expenses during the first nine months of 2015 as compared to the parallel period in 2014.

General and administrative expenses were NIS 6.79 million (U.S. \$1.73 million) for the nine months ended September 30, 2015 compared to NIS 7.73 million (U.S. \$1.97 million) for the same period in 2014. The decrease is primarily due to a reduction in salary and professional services expenses.

Financial expenses, net for the nine months ended September 30, 2015 aggregated NIS 4.70 million (U.S. \$1.20 million) compared to financial income, net of NIS 3.28 million (U.S. \$0.84 million) for the same period in 2014. The increase in financial expenses, net in the nine months of 2015 was mainly due to an increase in the fair value of warrants that are accounted as financial liability.

Can-Fite's net loss for the nine months ended September 30, 2015 was NIS 20.53 million (U.S. \$5.23 million) compared with a net loss of NIS 16.89 million (U.S. \$4.31 million) for the same period in 2014. The increase in net loss for the nine months of 2015, was primarily attributable to an increase in finance expenses, net offset by decreases in operating expenses.

As of September 30, 2015, Can-Fite had cash and cash equivalents of NIS 56.73 million (U.S. \$14.46 million) as compared to NIS 36.09 million (U.S. \$9.20 million) at December 31, 2014. The increase in cash during the nine months ended September 30, 2015 is due to NIS 32.35 million (\$8.25 million) received from issuance of shares and warrants, net of issuance expenses and NIS 5.14 million (U.S. \$1.31 million) received from Cipher Pharmaceuticals as upfront payment for entering into the distribution agreement with Cipher, offset by operating expenses. An additional \$4.3 million, net was raised in October 2015, following the end of the third quarter.

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, 2015 (U.S. \$ 1 = NIS 3.923).

The Company's consolidated financial results for the nine months ended September 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 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. 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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INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except share and per share data)

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

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	14,460	56,727	36,091
Accounts receivable and prepaid expenses	707	2,773	3,417
<u>Total current assets</u>	<u>15,167</u>	<u>59,500</u>	<u>39,508</u>
NON-CURRENT ASSETS:			
Lease deposits	5	17	26
Property, plant and equipment, net	64	252	133
<u>Total long-term assets</u>	<u>69</u>	<u>269</u>	<u>159</u>
<u>Total assets</u>	<u>15,236</u>	<u>59,769</u>	<u>39,667</u>

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
In thousands (except share and per share data)

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

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

Trade payables	263	1,032	1,024
Deferred revenues	276	1,082	-
Other accounts payable	905	3,548	4,750
<u>Total current liabilities</u>	<u>1,444</u>	<u>5,662</u>	<u>5,774</u>

NON-CURRENT LIABILITIES:

Warrants exercisable into shares	5,738	22,510	6,969
Deferred revenues	897	3,518	-
Severance pay, net	53	209	224
<u>Total long-term liabilities</u>	<u>6,688</u>	<u>26,237</u>	<u>7,193</u>

COMMITMENTS AND CONTINGENT LIABILITIES

SHAREHOLDERS' EQUITY

Share capital	1,651	6,475	5,441
Share premium	82,031	321,808	301,787

Capital reserve from share-based payment transactions

4,719	18,508	17,153
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Warrants exercisable into shares (series 9-12)

2,290	8,983	9,652
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Treasury shares

(925)	(3,628)	(3,628)
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Accumulated other comprehensive loss

(284)	(1,111)	(1,015)
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Accumulated deficit

(82,606)	(324,061)	(304,150)
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Equity attributable to equity holders of the Company

6,876	26,974	25,240
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Non-controlling interests

228	896	1,460
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Total shareholders' equity

7,104	27,870	26,700
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Total liabilities and shareholders' equity

15,236	59,769	39,667
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INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except share and per share data)

Convenience
translation
into
U.S. dollars

Nine months ended September 30,

2015	2015	2014
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Unaudited

USD

NIS

NIS

Revenues	<u>138</u>	<u>541</u>	<u>-</u>
Research and development expenses	2,442	9,580	12,441
General and administrative expenses	<u>1,732</u>	<u>6,793</u>	<u>7,729</u>
Operating loss	<u>4,036</u>	<u>15,832</u>	<u>20,170</u>
Finance expenses	1,239	4,862	515
Finance income	<u>(42)</u>	<u>(167)</u>	<u>(3,795)</u>
Net loss	<u>5,233</u>	<u>20,527</u>	<u>16,890</u>
Other comprehensive loss (income):			
Adjustments arising from translating financial statements of foreign operations	<u>30</u>	<u>117</u>	<u>485</u>
Total comprehensive loss	<u>5,263</u>	<u>20,644</u>	<u>17,375</u>
Loss attributable to:			
Equity holders of the Company	5,076	19,911	16,369
Non-controlling interests	<u>157</u>	<u>616</u>	<u>521</u>
	<u>5,233</u>	<u>20,527</u>	<u>16,890</u>

Comprehensive loss attributable to:

Equity holders of the Company

5,101	20,007	16,767
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Non-controlling interests

162	637	608
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5,263	20,644	17,375
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Net loss per share attributable to equity holders of the Company :

Basic and diluted net loss per share

0.24	0.93	0.95
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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-nine-months-ended-september-30-2015-300184807.html>

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