

April 1, 2016

# Can-Fite Reports 2015 Financial Results & Provides Clinical Pipeline Update

PETACH TIKVA, Israel, April 1, 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 announced it has filed its 2015 Annual Report on Form 20-F with the U.S. Securities and Exchange Commission.

Clinical Development Program and Corporate Highlights Include:

- ***CF101 – Preparing Phase III Trials in Rheumatoid Arthritis & Psoriasis Scheduled to Commence in 2016***

Can-Fite completed its Phase III trial protocol and Registration Plan for CF101 in the treatment of rheumatoid arthritis and submitted it to the European Medicines Agency (EMA) in March 2016. The Company anticipates commencing the trial in the second or third quarter of 2016.

The Phase III trial protocol for CF101 in the treatment of psoriasis is nearing completion, and is planned to be filed with the EMA in the first half of 2016, with study initiation expected in the fourth quarter of 2016.

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

Can-Fite continues to enroll and dose patients in its global Phase II liver cancer study in the U.S., Europe, and Israel. Completion of enrollment with approximately 78 patients is expected in the second half of 2016. In 2015, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to CF102 as a second line treatment for hepatocellular carcinoma (HCC) in patients who have previously received Nexavar (sorafenib). HCC is the most common form of liver cancer. CF102 has Orphan Drug Designation in the U.S. for HCC and in 2015 also received Orphan Drug Designation from the EMA for the indication of HCC.

Following compelling preclinical data reported in 2015 on CF102's efficacy in the treatment of non-alcoholic steatohepatitis (NASH), Can-Fite is preparing to file its Phase II protocol with institutional review boards (IRBs) in the second quarter of 2016. This new indication for CF102 addresses a market estimated to reach \$35-\$40 billion by 2025 according to Deutsche Bank.

- ***CF602 – Preparing to Submit IND to FDA for Treatment of Sexual Dysfunction***

Can-Fite is currently conducting further preclinical work for CF602 in the treatment of sexual dysfunction in preparation to submit an investigational new drug (IND) application to the FDA in the fourth quarter of 2016. In 2015, Can-Fite reported new findings showing CF602

demonstrated effects on erectile dysfunction superior to that of Viagra in animal studies.

- ***OphthaliX - Phase II Results for CF101 in Treatment of Glaucoma Expected in Q2 2016***

In 2015, Can-Fite's subsidiary OphthaliX completed patient enrollment in its Phase II trial for CF101 in the treatment glaucoma and related syndromes of ocular hypertension. The Company expects to report data from this study in the second quarter of 2016.

"We believe our portfolio of small molecule drug candidates has strong potential to address unmet needs in today's treatment markets. Having been tested in over 1,000 patients to date, our drugs have proven safe and shown efficacy in numerous clinical trials," stated Can-Fite CEO Dr. Prina Fishman. "We are continuing to conduct a very active clinical program designed to move several of these drugs towards regulatory approvals."

Revenues for the twelve months ended December 31, 2015 were NIS 0.64 million (\$0.16 million). We did not record any revenues during the year ended December 31, 2014. The increase in revenue was due to the recognition of a portion of the NIS 5.14 million (\$1.32 million) upfront payment received in March 2015 under the distribution agreement with Cipher Pharmaceuticals.

Research and development expenses for the twelve months ended December 31, 2015 were NIS 15.05 million (U.S. \$3.86 million) compared with NIS 16.2 million (U.S. \$4.15 million) for the same period in 2014. Research and development expenses for 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 2015 as compared to the parallel period in 2014.

General and administrative expenses were NIS 10.63 million (U.S. \$2.72 million) for the twelve months ended December 31, 2015 compared to NIS 11.57 million (U.S. \$2.97 million) for the same period in 2014. The decrease is primarily due to a reduction in salary and investor and public relations expenses.

Financial income, net for the twelve months ended December 31, 2015 aggregated NIS 5.29 million (U.S. \$1.36 million) compared to financial income, net of NIS 3.27 million (U.S. \$0.84 million) for the same period in 2014. The increase in financial income, net in 2015 was mainly due to a decrease in the fair value of warrants that are accounted as financial liability.

Can-Fite's net loss for the twelve months ended December 31, 2015 was NIS 19.77 million (U.S. \$5.07 million) compared with a net loss of NIS 24.52 million (U.S. \$6.28 million) for the same period in 2014. The decrease in net loss for 2015 was primarily attributable to decreases in operating expenses and an increase in financial income, net.

As of December 31, 2015, Can-Fite had cash and cash equivalents of NIS 66.03 million (U.S. \$16.92 million) as compared to NIS 36.09 million (U.S. \$9.25 million) at December 31, 2014. The increase in cash during the twelve months ended December 31, 2015 is due to NIS 48.33 million (U.S. \$12.39 million) raised from registered direct offerings in September and October 2015 and NIS 5.14 million (U.S. \$1.32 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 December 31, 2015 (U.S. \$ 1 = NIS 3.902).

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

The 2015 Annual Report can be found on the Company's website at [www.canfite.com](http://www.canfite.com) as well as on the SEC website at [www.sec.gov](http://www.sec.gov). In addition, security holders may request a hard copy of the Annual Report, which includes the Company's complete audited financial statements, free of charge. Requests can be made by contacting Can-Fite Investor Relations at 10 Bareket Street, Kiryat Matalon, Petah-Tikva 4951778, Israel or by phone at +972-3-9241114.

### **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 drug candidate is scheduled to enter Phase III trials in 2016 for two indications, rheumatoid arthritis and psoriasis. 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.canfite.com](http://www.canfite.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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