

September 2, 2014

Can-Fite Reports First Six Months 2014 Results

PETACH TIKVA, Israel, Sept. 2, 2014 /PRNewswire/ -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory and cancer diseases, today reported financial results for the six months ended June 30, 2014 and updates on its clinical programs.

Clinical and Corporate Highlights Include:

- ***CF101 – Completes patient enrollment in Phase II/III trial for the treatment of psoriasis***

Can-Fite has completed enrollment of over 300 patients at 17 clinical centers in the U.S., Europe, and Israel in its Phase II/III trial for the treatment of psoriasis. Top line results from the trial are expected in the first quarter of 2015.

- ***CF102 – FDA agrees to Phase II liver cancer trial protocol***

During the quarter, Can-Fite submitted to the U.S. Food and Drug Administration (FDA) the protocol for its global Phase II trial for the treatment of advanced hepatocellular carcinoma (HCC) with Child-Pugh Class B cirrhosis. The planned Phase II study will be conducted in Israel, Europe and the U.S. with 78 subjects and will investigate the efficacy and safety of CF102 as compared to placebo. Following Can-Fite's submission, the FDA agreed with the protocol design. The FDA had also previously granted Can-Fite Orphan Drug designation for CF102 in this indication.

- ***CF102 – EU grants patent for treatment of liver function following surgery***

The European Union granted Can-Fite a patent for its invention titled, "Method for inducing hepatocyte proliferation and uses thereof." The patent covers CF102 in the treatment of liver function following liver resection (surgery) by helping the liver to regenerate and repair itself. Preclinical studies have found CF102 offers potential efficacy not only for cancer patients after a tumor has been surgically removed from the liver, it may also offer important benefits for patients with other kinds of liver diseases.

- ***A3AR - Begins development of biomarker test kit***

Can-Fite is developing a commercial biomarker blood test kit for the A3 adenosine receptor (A3AR) predictive biomarker. The kit is designed for use at any molecular biology lab prior to treatment to help identify an individual patient's responsiveness to the Company's drugs, thus providing personalized medicine. The U.S. Patent and Trademark Office had previously issued Can-Fite a patent for A3AR as a biomarker to predict patient response to CF101 in autoimmune inflammatory indications.

"In the second quarter we moved forward with meaningful advances in each of our clinical

programs, including preparing for our Phase II liver cancer trial for CF102, designing the clinical study protocol for our Phase III rheumatoid arthritis trial for CF101, as well as completing patient enrollment in our Phase II/III psoriasis trial," stated Can-Fite CEO Dr. Pnina Fishman.

"Subsequent to the end of the second quarter, Israel's Ministry of Health approved CF102 for Compassionate Use for a liver cancer patient who has already benefitted from the drug during clinical trials. We were also pleased to discover, through a retrospective analysis of CF101 in our autoimmune disease trials, the drug shows high efficacy based on a patient's body mass index. This is very important data that we believe will optimize the design of our upcoming Phase III rheumatoid arthritis trial," Fishman concluded.

Research and development expenses for the six months ended June 30, 2014 were NIS 8.64 million (U.S. \$2.51 million) compared with NIS 7.66 million (U.S. \$2.23 million) for the same period in 2013. Research and development expenses for the first half of 2014 comprised primarily of expenses associated with the initiation of a planned Phase II study for CF102 as well as expenses for pre-clinical studies of CF102.

General and administrative expenses were NIS 5.42 million (U.S. \$1.58 million) for the six months ended June 30, 2014 and NIS 6.59 million (U.S. \$1.92 million) for the same period in 2013. The decrease is primarily due to a reduction in share based compensation expenses.

Financial income, net for the six months ended June 30, 2014 aggregated NIS 1.71 million (U.S. \$0.50 million) compared to financial expenses, net of NIS 0.03 million (U.S. \$0.01 million) for the same period in 2013. The increase in financial income, net in the first half of 2014 was mainly due to a decrease in the fair value of the Company's warrants.

Can-Fite's loss for the six months ended June 30, 2014 was NIS 12.36 million (U.S. \$3.59 million) compared with a loss of NIS 14.29 million (U.S. \$4.15 million) for the same period in 2013. The decrease in net loss for the first half of 2014, was attributable to an increase in finance income, net.

As of June 30, 2014, Can-Fite had cash and cash equivalents of NIS 19.19 million (U.S. \$5.58 million) as compared to NIS 20.77 million (U.S. \$6.04 million) at December 31, 2013. The company raised NIS 15.9 million (U.S. \$4.62 million) during the first half of 2014. The decrease in cash during that period was due to cash used to finance the operations exceeding the raised amount.

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, 2014 (U.S. \$ 1 = NIS 3.438).

The Company's consolidated financial results for the six months ended June 30, 2014 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 and inflammatory diseases. The Company's CF101 is in Phase II/III trials for the treatment of psoriasis and the Company is preparing for

a Phase III CF101 trial for rheumatoid arthritis. Can-Fite's liver cancer drug CF102 is commencing 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. 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.

Contact

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

| | <u>June 30, 2014</u> | <u>June 30, 2014</u> | <u>December 31, 2013</u> |
|------------------------------------|--------------------------|--------------------------|------------------------------|
| | <u>Unaudited</u> | <u>Unaudited</u> | <u>Audited</u> |
| | <u>In thousands</u> | <u>NIS in thousands</u> | |
| ASSETS | | | |
| CURRENT ASSETS: | | | |
| Cash and cash equivalents | 5,580 | 19,185 | 20,767 |
| Accounts receivable | 790 | 2,716 | 2,161 |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> current assets | 6,370 | 21,901 | 22,928 |
| | <hr/> | <hr/> | <hr/> |
| NON-CURRENT ASSETS: | | | |
| Lease deposits | 10 | 34 | 34 |
| Property, plant and equipment, net | 43 | 147 | 143 |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> long-term assets | 53 | 181 | 177 |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> assets | 6,423 | 22,082 | 23,105 |

The accompanying notes are an integral part of the interim condensed consolidated financial statements.

Convenience
translation
into
U.S. dollars.

| | June 30, | June 30, | December 31, |
|---|--------------|------------------|--------------|
| | 2014 | 2014 | 2013 |
| | Unaudited | Unaudited | Audited |
| | In thousands | NIS in thousands | |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | | |
| CURRENT LIABILITIES: | | | |
| Trade payables | 549 | 1,887 | 2,056 |
| Other accounts payable | 739 | 2,540 | 5,276 |
| Warrants exercisable into shares (series 7) | - | - | 119 |
| <u>Total</u> current liabilities | 1,288 | 4,427 | 7,451 |
| NON-CURRENT LIABILITIES: | | | |
| Warrants exercisable into shares | 456 | 1,569 | - |
| Severance pay, net | 36 | 125 | 129 |
| <u>Total</u> long-term liabilities | 492 | 1,694 | 129 |
| EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY: | | | |
| Share capital | 1,319 | 4,535 | 4,037 |

| | | | |
|---|----------|-----------|-----------|
| Share premium | 81,354 | 279,694 | 267,946 |
| Capital reserve from share-based payment transactions | 4,729 | 16,257 | 15,761 |
| Warrants exercisable into shares (series 9-12) | 2,807 | 9,652 | 9,652 |
| Treasury shares at cost | (1,055) | (3,628) | (3,628) |
| Accumulated other comprehensive loss | (29) | (99) | (151) |
| Accumulated deficit | (85,051) | (292,405) | (280,391) |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> equity attributable to equity holders of the Company | 4,074 | 14,006 | 13,226 |
| | <hr/> | <hr/> | <hr/> |
| Non-controlling interests | 569 | 1,955 | 2,299 |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> shareholders' equity | 4,643 | 15,961 | 15,525 |
| | <hr/> | <hr/> | <hr/> |
| <u>Total</u> liabilities and shareholders' equity | 6,423 | 22,082 | 23,105 |
| | <hr/> | <hr/> | <hr/> |

The accompanying notes are an integral part of the interim condensed consolidated financial statements.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | | |
|--|--|------------------------------|
| | Convenience translation into U.S. dollars | |
| | Six months ended June 30, | Six months ended June 30, |
| | <hr/> | <hr/> |

| | 2014 | 2014 | 2013 |
|--|--------------|---|--------|
| | Unaudited | | |
| | In thousands | NIS in thousands (except per share data) | |
| Research and development expenses | 2,512 | 8,636 | 7,663 |
| General and administrative expenses | 1,578 | 5,425 | 6,591 |
| Operating loss | 4,090 | 14,061 | 14,254 |
| Finance expenses | 228 | 780 | 445 |
| Finance income | (723) | (2,485) | (412) |
| Loss | 3,595 | 12,356 | 14,287 |
| Other comprehensive loss (income): | | | |
| Exchange differences of foreign operations | (19) | (65) | 291 |
| Total comprehensive loss | 3,576 | 12,291 | 14,578 |
| Loss attributable to: | | | |
| Equity holders of the Company | 3,496 | 12,014 | 13,125 |
| Non-controlling interests | 99 | 342 | 1,162 |

| | | | |
|--|--------------|---------------|---------------|
| | <u>3,595</u> | <u>12,356</u> | <u>14,287</u> |
| Total comprehensive loss attributable to: | | | |
| Equity holders of the Company | 3,480 | 11,962 | 13,364 |
| Non-controlling interests | <u>96</u> | <u>329</u> | <u>1,214</u> |
| | <u>3,576</u> | <u>12,291</u> | <u>14,578</u> |
| Net loss per share attributable to equity holders of the Company : | | | |
| Basic and diluted net loss per share | <u>0.21</u> | <u>0.71</u> | <u>1.11</u> |

The accompanying notes are an integral part of the interim condensed consolidated financial statements.

SOURCE Can-Fite BioPharma Ltd.