Can-Fite Reports Financial Results for Nine Months Ended September 30, 2014

PETACH TIKVA, Israel, Dec. 1, 2014 /PRNewswire/ -- <u>Can-Fite BioPharma Ltd</u>. (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 nine months ended September 30, 2014 and updates on its clinical programs.

Clinical and Corporate Highlights Include:

• CF101 – Data release from the Psoriasis Phase II/III study

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. Can-Fite has already received positive interim data from the first 100 patients. In addition, Can-Fite is planning a Phase III trial for rheumatoid arthritis based on the positive data of its Phase II study. Data from the Phase II ongoing glaucoma study (aimed at 88 patients) is expected to be released in Q2/Q3 2015.

• CF102 – Initiation of global Phase II Liver Cancer study

A global Phase II trial for the treatment of patients with advanced hepatocellular carcinoma (HCC) will be initiated in the US, Europe and Israel. The study will entail 78 subjects and will investigate the efficacy and safety of CF102 given as a second line therapy in patients with Child Pugh B liver cirrhosis as compared to placebo.

• Development of a kit to analyze A3 adenosine receptor, utilized as a predictive biomarker

Can-Fite is developing a commercial biomarker blood test kit for the A3 adenosine receptor (A3AR) predictive biomarker. The kit is designed to look at the A3 adenosine receptor expression levels prior to treatment with CF101 and predict patient's response to the drug. The U.S. Patent and Trademark Office had previously issued Can-Fite a patent for the utilization of A3AR as a biomarker to predict patients' response to CF101 in all autoimmune inflammatory indications.

Can-Fite CEO Dr. Pnina Fishman commented on the Company's recent achievements, stating, "In the third quarter, we moved forward with meaningful advances in each of our clinical programs and we are expecting to release data from our Phase II/III psoriasis trial during the first quarter of 2015. Subsequent to the end of the second quarter of 2014, 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."

Research and development expenses for the nine months ended September 30, 2014 were NIS 12.44 million (U.S. \$3.37 million) compared with NIS 10.19 million (U.S. \$2.76 million) for the same period in 2013. Research and developments expenses for the first nine months of 2014 comprised primarily of expenses associated with the initiation of a planned Phase II

study for liver cancer treatment with CF102, ongoing Phase II/II study for psoriasis treatment with CF101 as well as expenses for pre-clinical studies of CF102 and CF101.

General and administrative expenses were NIS 7.73 million (U.S. \$2.09 million) for the nine months ended September 30, 2014 and NIS 9.61 million (U.S. \$2.60 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 nine months ended September 30, 2014 aggregated NIS 3.28 million (U.S. \$0.89 million) compared to financial income, net of NIS 0.21 million (U.S. \$0.06 million) for the same period in 2013. The increase in financial income, net in the first nine months of 2014 was mainly due to a decrease in the fair value of the Company's warrants.

Can-Fite's loss for the first nine months ended September 30, 2014 was NIS 16.89 million (U.S. \$4.57 million) compared to a loss of NIS 19.58 million (U.S. \$5.30 million) for the same period in 2013. The decrease in net loss for the first nine months of 2014, was attributable to an increase in finance income, net.

As of September 30, 2014, Can-Fite had cash and cash equivalents of NIS 15.22 million (U.S. \$4.12 million) as compared to NIS 20.77 million (U.S. \$5.62 million) at December 31, 2013. The Company raised a net total of NIS 15.77 million (U.S. \$4._27 million) during the first nine month of 2014 from Can-Fite's private placement during the three months ended March 31, 2014. The decrease in cash during that period was due to cash used to finance the operations exceeding the amount raised.

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, 2014 (U.S. \$ 1 = NIS 3.695).

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

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CAN-FITE BIOPHARMA LTD. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Convenience

In thousands

 translation

 Into
 U.S. dollars

 September 30, 2014
 September 30, 2014
 December 31, 2013

 Unaudited
 Unaudited
 Audited

NIS in thousands

ASSETS

CURRENT ASSETS:

| Cash and cash equivalents | 4,118 | 15,215 | 20,767 |
|------------------------------------|-------|--------|--------|
| Accounts receivable | 688 | 2,544 | 2,161 |
| <u>Total</u> current assets | 4,806 | 17,759 | 22,928 |
| NON-CURRENT ASSETS: | | | |
| Lease deposits | 9 | 34 | 34 |
| Property, plant and equipment, net | 38 | 139 | 143 |
| <u>Total</u> long-term assets | 47 | 173 | 177 |
| <u>Total</u> assets | 4,853 | 17,932 | 23,105 |

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

CAN-FITE BIOPHARMA LTD. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Convenience translation Into
U.S. dollars.

| September 30, | September 30, | December 31, | |
|---------------|------------------|--------------|--|
| 2014 | 2014 | 2013 | |
| Unaudited | Unaudited | Audited | |
| In thousands | NIS in thousands | | |

LIABILITIES AND SHAREHOLDERS' EQUITY

Capital reserve from share-based payment transactions

Warrants exercisable into shares (series 9-12)

Treasury shares at cost

| CURRENT LIABILITIES: | | | |
|---|--------|---------|---------|
| Trade payables | 682 | 2,520 | 2,056 |
| Other accounts payable | 779 | 2,876 | 5,276 |
| Warrants exercisable into shares (series 7) | - | | 119 |
| <u>Total</u> current liabilities | 1,461 | 5,396 | 7,451 |
| NON-CURRENT LIABILITIES: | | | |
| Warrants exercisable into shares | 374 | 1,383 | - |
| Severance pay, net | 36 | 131 | 129 |
| <u>Total</u> long-term liabilities | 410 | 1,514 | 129 |
| EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY: | | | |
| Share capital | 1,229 | 4,542 | 4,037 |
| Share premium | 75,731 | 279,825 | 267,946 |

16,203

9,652

(3,628)

4,385

2,612

(982)

15,761

9,652

(3,628)

| Accumulated other comprehensive loss | (149) | (549) | (151) |
|--|----------|-----------|-----------|
| Accumulated deficit | (80,314) | (296,760) | (280,391) |
| Total equity attributable to equity holders of the Company | 2,512 | 9,285 | 13,226 |
| Non-controlling interests | 470 | 1,737 | 2,299 |
| <u>Total</u> shareholders' equity | 2,982 | 11,022 | 15,525 |
| <u>Total</u> liabilities and shareholders' equity | 4,853 | 17,932 | 23,105 |

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

CAN-FITE BIOPHARMA LTD. AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | Unaudited | | |
|---------------|---------------|------|--|
| 2014 | 2014 | 2013 | |
| September 30, | September 30, | | |
| ended | ended | | |
| Nine months | Nine months | | |
| dollars | | | |
| into U.S. | | | |
| translation | | | |
| Convenience | | | |

| | In thousands | NIS in thousands (except per share data) | |
|--|--------------|--|--------|
| | | | |
| Research and development expenses | 3,367 | 12,441 | 10,185 |
| General and administrative expenses | 2,092 | 7,729 | 9,605 |
| Operating loss | 5,459 | 20,170 | 19,790 |
| Finance expenses | 140 | 515 | 374 |
| Finance income | (1,027) | (3,795) | (584) |
| Loss | 4,572 | 16,890 | 19,580 |
| Other comprehensive loss (income): | | | |
| Exchange differences of foreign operations | 131 | 485 | 245 |
| Total comprehensive loss | 4,703 | 17,375 | 19,825 |
| Loss attributable to: | | | |
| Equity holders of the Company | 4,431 | 16,369 | 18,012 |
| Non-controlling interests | 141 | 521 | 1,568 |
| | 4,572 | 16,890 | 19,580 |

Total comprehensive loss attributable to:

Equity holders of the Company

| | 4,538 | 16,767 | 18,213 |
|--|-------|--------|--------|
| Non-controlling interests | | | |
| Non-controlling interests | 165 | 608 | 1,612 |
| | 4,703 | 17,375 | 19,825 |
| Net loss per share attributable to equity holders of the Company : | | | |
| Basic and diluted net loss per share | | | |
| | 0.26 | 0.95 | 1.38 |

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

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-30-2014-300002331.html

SOURCE Can-Fite BioPharma Ltd.