

Can-Fite Reports First Quarter 2019 Financial Results & Provides Clinical Update

- *Preparatory work for an end-of-Phase II FDA meeting to initiate a Phase III study in liver cancer is ongoing*
- *Top-line data from Phase II NASH study with Namodenoson expected in H2 2019*
- *Patient enrollment continues in two Phase III studies for Piclidenoson in the treatment of rheumatoid arthritis and psoriasis*

PETACH TIKVA, Israel--(BUSINESS WIRE)--[Can-Fite](#) BioPharma Ltd. (NYSE American: CANF) (TASE:CFBI), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address cancer, liver and inflammatory diseases, today announced financial results for the three months ended March 31, 2019.

Clinical Development and Corporate Highlights During Q1 2019 Include:

- **Top Line Results from Phase II Trial of Namodenoson in Liver Cancer-** Namodenoson was found to increase overall survival in hepatocellular carcinoma (HCC) patients with Child Pugh B7, the largest subpopulation of the study, as compared to placebo, even though the trial did not meet its primary endpoint. The Company is now preparing for an end-of-Phase II meeting with the FDA to initiate a Phase III study in liver cancer.
- **Liver Cancer Data Presentations Accepted at Leading Scientific Conferences-** Findings from the Phase II study have been accepted for presentation at two medical conferences that are highly influential in the field of liver cancer. Can-Fite is scheduled to deliver a late-breaking oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting on June 2 and is scheduled to deliver an oral presentation at the International Liver Cancer Association (ILCA) annual meeting on September 22.
- **Additional Distribution Deal for Namodenoson in Korea-** Can-Fite expanded its distribution deal for Namodenoson with Chong Kun Dang Pharmaceuticals (CKD) in South Korea to include the indication of NASH, in addition to the original distribution deal with CKD for Namodenoson in the treatment of liver cancer. For the expanded distribution, CKD paid Can-Fite \$1,000,000 upfront, with up to an additional \$5,000,000 due upon completion of milestones.
- **Manuscript on Can-Fite's Drugs in CAR-T Published -** Drug Design, Development and Therapy published an article about Can-Fite's drugs' potential ability to treat Cytokine Release Syndrome (CRS), a potentially fatal side effect of CAR-T and other immune-oncology therapies.
- **New Patent Granted in U.S. -** The U.S. Patent and Trademark Office issued a Notice of Allowance for Can-Fite's patent application titled, "Use of A3 adenosine receptor agonist in the treatment of Osteoarthritis." The patent addresses methods for treating osteoarthritis with A3 adenosine receptor (A3AR) agonists and has been granted to

Can-Fite in major global markets including North and South America, Europe and Asia.

- **Up-Front Money from Newly Signed Deal and Equity Fund Raise-** Following the end of the first quarter, Can-Fite received approximately \$10.2 million in gross proceeds of which \$1 million was received from CKD for the expanded distribution of Namodenoson in South Korea in April and \$9.2 million was raised through two registered direct offerings that were completed in April and May. Effective May 10, 2019, Can-Fite changed the ratio of its American Depositary Shares (ADSs) to ordinary shares from one ADS representing two ordinary shares to a new ratio of one ADS representing 30 ordinary shares.

“We are effectively advancing our drug pipeline through late stage clinical trials including two Phase III studies for Piclidenoson in autoimmune diseases and a planned Phase III for Namodenoson in liver cancer. In the coming months we expect to announce top line results from our Phase II study of Namodenoson in the treatment of NASH,” stated Can-Fite CEO Pnina Fishman. “Each one of the four indications we are pursuing addresses unmet needs in multi-billion dollar markets.”

Financial Results

Revenues for the three months ended March 31, 2019 were \$0.30 million compared to revenues of \$0.63 million during the three months ended March 31, 2018. The decrease in revenues for the first quarter of 2019 was mainly due to the recognition of a \$0.3 million advance payment received in January 2018 under the Distribution and Supply Agreement with Gebro compared to none in 2019.

Research and development expenses for the three months ended March 31, 2019 were \$1.44 million compared with \$1.31 million for the same period in 2018. Research and development expenses for the first quarter of 2019 comprised primarily of expenses associated with the Phase II studies for Namodenoson as well as expenses for ongoing studies of Piclidenoson. The increase is primarily due to increased costs associated with the initiation of the Phase III clinical trial of Piclidenoson for the treatment of rheumatoid arthritis.

General and administrative expenses were \$0.57 million for the three months ended March 31, 2019 compared to \$0.90 million for the same period in 2018. The decrease is primarily due to a decrease in professional services and investor relations expenses.

Financial expense, net for the three months ended March 31, 2019 was \$0.12 million compared to financial expense, net of \$0.13 million for the same period in 2018. The decrease in financial expense, net in the first quarter of 2019 is considered immaterial.

Can-Fite's net loss for the three months ended March 31, 2019 was \$1.83 million compared with a net loss of \$1.72 million for the same period in 2018. As of March 31, 2019, Can-Fite had cash and cash equivalents of \$2.96 million as compared to \$3.62 million at December 31, 2018. The decrease in cash during the three months ended March 31, 2019 is due to a decrease in net cash used in operating activity of \$1.46 million and a decrease in net cash provided by financing activity of \$2.4 million.

In April and May 2019, the Company raised \$3.2 million and \$6 million in gross proceeds, respectively, in registered direct offerings.

The Company's consolidated financial results for the three months ended March 31, 2019 are presented in accordance with International Financial Reporting Standards.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

| | March 31, 2019 Unaudited USD | December 31, 2018 Audited |
|---------------------------------------|---------------------------------------|------------------------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | 2,956 | 3,615 |
| Other receivable and prepaid expenses | 4,234 | 4,015 |
| Short-term investment | 250 | 273 |
| Total current assets | 7,440 | 7,903 |
| NON-CURRENT ASSETS: | | |
| Lease deposits | 5 | 2 |
| Property, plant and equipment, net | 44 | 47 |
| Total long-term assets | 49 | 49 |
| Total assets | 7,489 | 7,952 |

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

In thousands (except for share and per share data)

March 31, December
31,

| | |
|------------------|----------------|
| 2018 | 2018 |
| Unaudited | Audited |
| USD | |

LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES:

| | | |
|-------------------------------|-----------|-----------|
| Trade payables | \$ 1,296 | \$ 1,071 |
| Deferred revenues | 1,000 | 926 |
| Other accounts payable | 409 | 1,122 |
| Total current liabilities | 2,705 | 3,119 |

NON-CURRENT LIABILITIES:

| | | |
|---------------------------------|-----------|-----------|
| Deferred revenues | 1,539 | 1,818 |
| Total long-term liabilities | 1,539 | 1,818 |

CONTINGENT LIABILITIES AND COMMITMENTS

EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:

| | | |
|---|--------------|--------------|
| Share capital | 2,939 | 2,635 |
| Share premium | 95,761 | * 94,076 |
| Capital reserve from share-based payment transactions | 5,873 | 5,800 |
| Accumulated other comprehensive income | 1,127 | 1,127 |
| Accumulated deficit | (102,455) | (100,623) |
| Total equity | 3,245 | 3,015 |
| Total liabilities and equity | \$ 7,489 | \$ 7,952 |

(*) Warrants exercisable into shares as of December 31, 2018 were reclassified into Share premium.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

| | Three months ended | |
|--|---------------------------|-------------|
| | March 31, | |
| | 2019 | 2018 |
| | Unaudited | |
| | USD | |
| Revenues | \$ 299 | \$ 632 |
| Research and development expenses | 1,443 | 1,313 |
| General and administrative expenses | 567 | 907 |
| Operating loss | 1,711 | 1,588 |
| Finance expenses | 130 | 139 |
| Finance income | (9) | (6) |
| Total Financial expenses, net | 121 | 133 |
| Net loss | 1,832 | 1,721 |
| Net loss per share attributable to equity holders of the Company | | |
| : | | |
| Basic and diluted net loss per share | (0.04) | (0.05) |

About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE American: 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 currently in Phase III trials for rheumatoid arthritis and psoriasis. Can-Fite's liver cancer drug, Namodenoson, recently completed a Phase II trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and is in a Phase II trial 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 HCC 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 the Company is investigating additional compounds, targeting A3AR, for the treatment of sexual dysfunction. 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, market risks and uncertainties, 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. Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; statements as to the impact of the political and security situation in Israel on our business; and risks and other risk factors detailed 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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