

January 6, 2020

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# Can-Fite CEO Issues Letter to Shareholders

- ***Q1 2020: Topline results from NASH Phase II study expected***
- ***Advanced stage clinical pipeline positioned to potentially generate more non-dilutive funding through out-licensing distribution agreements***
- ***Two Phase III studies enrolling in psoriasis and rheumatoid arthritis***

PETACH TIKVA, Israel--(BUSINESS WIRE)-- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE:CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, issued a Letter to Shareholders from the Company's Chief Executive Officer, Pnina Fishman, Ph.D.

Dear Can-Fite Shareholders,

We made significant progress in our drug development programs during 2019 and are entering 2020 with the expectation of major value-driving events over the next 12 months.

**Namodenoson NASH top line results expected Q1 2020**- Namodenoson's Phase II study in NASH (non-alcoholic steatohepatitis) completed enrollment, and we expect to announce top line results in the first quarter of 2020.

**Namodenoson Phase III study design for liver cancer receives FDA's agreement**– We successfully concluded an End of Phase II meeting with the U.S. FDA for Namodenoson in the treatment of advanced liver cancer. We are now preparing a Phase III study in this indication. The FDA has agreed with our Phase III study design, which is based on the efficacy shown from our Phase II data in the sub-population of patients with underlying Child Pugh B7 cirrhosis.

**Namodenoson is approved for use in Israel under Compassionate Use Program**– We recently initiated Namodenoson's Compassionate Use Program in Israel, which allows doctors and their patients the option of early access to investigational new drugs under closely controlled and monitored circumstances when a patient who is facing serious illness has exhausted all available treatment options. Namodenoson has been out-licensed for the indications of liver cancer and NASH in South Korea, China, Hong Kong, Macau, and Taiwan.

**Namodenoson has potential utilization as anti-obesity drug based on new data** - New pre-clinical studies of Namodenoson conducted at Hadassah Medical Center demonstrate the drug induces weight loss and normalizes glucose levels in experimental models. Based on these results, Can-Fite filed a PCT patent for Namodenoson as an anti-obesity drug. The global obesity treatment market is expected to exceed [\\$12 billion](#) by 2023 according to Market Research Future.

**Piclidenoson progresses in Phase III studies**- Piclidenoson is now being evaluated in two Phase III trials in psoriasis and rheumatoid arthritis, enrolling approximately 400 and 500

patients in each study, respectively. We completed enrollment of over 50% of patients in our psoriasis study. Prior Phase II data of Piclidenoson have been thoroughly reviewed by regulatory agencies prior to the start of our Phase III studies, and the data have been vetted by our distribution partners who have paid upfront and milestone payments in exchange for the right to market Piclidenoson, upon regulatory approval, in their respective markets in Canada, Spain, Austria, Switzerland, South Korea, Hong Kong, Macau, Taiwan, and China. We look forward to announcing updates for the ongoing trials during the year.

**Out-licensing our drugs for non-dilutive funding** - Our business strategy is strongly supported by our advanced stage Phase II and Phase III clinical trials and results. The efficacy and safety data produced in over 1,000 patients gives our distribution partners the confidence to enter into partnership agreements with Can-Fite. Upfront and milestone payments from our distribution partners provide non-dilutive funding for Can-Fite, while also building a global distribution network for our drugs. To date, we have received over \$18 million in upfront and milestone payments from distribution partners. These established agreements include double-digit royalties upon regulatory approval, as well as the potential for numerous additional payments to Can-Fite based upon achieving clinical regulatory milestones. While we are very pleased to have partnered in some key territories, we aim to sign additional agreements in the largest markets including the U.S., South America, Europe, and Asia. Our clinical development pipeline targets indications with multi-billion-dollar markets.

**Additional value creating opportunities with strategic partners** - (a) Erectile dysfunction: We have built strong IP assets and preclinical data around our erectile dysfunction drug candidate, CF602 which is well positioned for a development partnership with a pharma company looking to develop a drug in this indication that can safely be used by people living with diabetes; (b) Osteoarthritis in canines: Piclidenoson has recently garnered attention and interest from veterinary medicine companies for osteoarthritis in canines; and (c) Cannabis: We are working with our strategic partner Univo Pharmaceuticals to develop new cannabis-based pharmaceuticals. This partnership was strengthened in December 2019, when Univo's CEO Golan Bitton joined Can-Fite's board of directors. Each of these opportunities have the potential to create additional value for Can-Fite through partnerships, without entering clinical trials directly managed by our Company.

We thank all of our shareholders for their ongoing support as we execute on our out-licensing strategy. Leveraging our advanced-stage clinical assets into distribution deals that generate near and long-term non-dilutive funds, we aim to build value for shareholders while developing much needed treatments for people living with chronic diseases.

Sincerely,

Pnina Fishman, Ph.D.

Chief Executive Officer

### **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. 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](http://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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Source: Can-Fite BioPharma Ltd.