March 25, 2021

Can-Fite Reports 2020 Financial Results & Provides Clinical Development Update

$5M cash infusion received in warrant exercises and upfront money from a licensing deal

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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 inflammatory, cancer and liver diseases, today announced financial results for the year ended December 31, 2020.

Clinical Developments and Corporate Highlights Include:

Cash Infusion of $5 Million – During the first quarter of 2021, Can-Fite received $2.75 million in February and March 2021 through warrant exercises and $2.25 million in an upfront payment in March 2021 from a new distribution agreement with Ewopharma.

Out-licensing Deal Worth $42.7 Million with Ewopharma – Can-Fite signed its latest out-licensing agreement with Swiss-based Ewopharma for distribution of its drug candidates in Central Eastern Europe and Switzerland. Can-Fite received $2.25 million upfront with up to an additional $40.45 million payable upon the achievement of regulatory and sales milestones, plus 17.5% royalties on net sales.

Phase II COVID-19 Study Enrolling Patients – Can-Fite is enrolling 40 patients in its Phase II study under a U.S. Food and Drug Administration (FDA) approved protocol in patients hospitalized with moderate to severe COVID-19. Patients are randomized in a 1:1 ratio to receive 2 mg Piclidenoson twice daily or placebo, and treated for up to 28 days.

Phase III Psoriasis Study Continues to Enroll Based on Positive Interim Analysis – In October 2020, the Independent Data Monitoring Committee for Can-Fite's Phase III trial of Piclidenoson in the treatment of moderate-to-severe plaque psoriasis reviewed the blinded study data and recommended the Company continue to enroll patients. The majority of costs associated with the Phase III Comfort™ study have been previously paid.

Phase IIb NASH Study Expected to Commence Q4 2021 – Based on a successfully concluded Phase IIa NASH/NAFLD study with Namodenoson which met its primary endpoint, Can-Fite is working closely with top Key Opinion Leaders in liver disease to complete its study design for a Phase IIb study. Can-Fite expects to commence the study before the end of 2021.

Pivotal Phase III Liver Cancer Study Expected to Commence Q4 2021- Can-Fite has reached agreements with the U.S. FDA and the European Medicines Agency on the protocol of a pivotal Phase III study for the treatment of hepatocellular carcinoma (HCC), the most

common form of liver cancer. Should the study meet its efficacy endpoint and be approved by the FDA and EMA, Namodenoson would become one of only a few drugs available to treat advanced liver cancer patients.

“2020 was a pivotal year for Can-Fite as we demonstrated a robust clinical proof of concept for both Piclidenoson and Namodenoson,” stated Can-Fite CEO Dr. Pnina Fishman. “We advanced our pipeline and are firmly focused on Psoriasis, NASH, Advanced Liver Cancer, and COVID-19. We continue to collaborate with distribution and out-licensing partners in select territories, thereby securing distribution for our drugs upon approval and generating revenues through upfront money and milestone payments. We are excited to potentially deliver on additional significant milestones in 2021.”

Financial Results

Revenues for the year ended December 31, 2020 were $0.76 million, a decrease of $1.27 million, or 63%, compared to $2.03 million for the year ended December 31, 2019. The decrease in revenues was mainly due to the recognition of a lower portion of advance payments received under distribution agreements from Gebro, Chong Kun Dung Pharmaceuticals, and Cipher Pharmaceuticals.

Research and development expenses for the year ended December 31, 2020 were $11.95 million, an increase of $0.98 million, or 8.9%, compared to $10.97 million for the year ended December 31, 2019. Research and developments expenses for the year ended 2020 comprised primarily of expenses associated with the Phase II studies for Namodenoson in the treatment of NASH and HCC, as well as expenses for ongoing Phase III studies of Piclidenoson in the treatment of rheumatoid arthritis and psoriasis. The increase is primarily due to increased costs associated with the accelerating rate of absorption of patients for the Phase III clinical trial of Piclidenoson for the treatment of rheumatoid arthritis and for psoriasis. We expect that the research and development expenses will increase through 2021 and beyond.

General and administrative expenses were $2.95 million for the year ended December 31, 2020 a decrease of $0.11 million, or 3.6%, compared to $3.06 million for the year ended December 31, 2019. The decrease is primarily due to the decrease in professional services and travel expenses which was partly offset by an increase in salaries and related benefits and insurance expenses. We expect that general and administrative expenses will remain at the same level through 2021.

Financial expense, net for the year ended December 31, 2020 aggregated $0.3 million compared to $0.6 million for the year ended December 31, 2019. The decrease in financial expense, net was mainly due to a decrease in the revaluation of our short-term investment.

Net loss for the year ended December 31, 2020 was $14.44 million compared with a net loss of $12.62 million for the year ended December 31, 2019. The increase in net loss for the year ended December 31, 2020 was primarily attributable to a decrease in revenues in 2020 and an increase in research and development expenses which were partly offset by a decrease in finance expenses, net.

As of December 31, 2020, Can-Fite had cash and cash equivalents of $8.26 million as compared to $2.69 million at December 31, 2019. The increase in cash during the year

ended December 31, 2020 is due to an aggregate of $17.68 million in net proceeds received through a warrant exercise transaction in January 2020, a public offering in February 2020, partial exercises in March, April, and May 2020 of warrants issued in the February 2020 public offering, and a registered direct offering in June and July 2020 which was offset by net cash used in operating activity of $12.06 million.

More detailed information can be found in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2020, a copy of which has been filed with the Securities and Exchange Commission (SEC). The Annual Report, which contains the Company's audited consolidated financial statements, can be accessed on the SEC's website at http://www.sec.gov/ as well as via the Company's investor relations website at https://ir.canfite.com. The Company will deliver a hard copy of its Annual Report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Can-Fite Investor Relations at 10 Bareket Street, Kiryat Matalon, Petah-Tikva 4951778, Israel or by phone at +972-3-9241114.

CONSOLIDATED BALANCE SHEETS

In thousands (except for share and per share data)

	December 31,	
	2020	**2019**
	USD	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 8,268	$ 2,697
Other accounts receivables and prepaid expenses	1,057	4,383
Short-term investment	75	64
Total current assets	9,400	7,144
NON-CURRENT ASSETS:		
Other non-current receivables	-	912
Right to use asset	73	82
Property, plant and equipment, net	50	36
Total long-term assets	123	1,030
Total assets	$ 9,523	$ 8,174

CONSOLIDATED BALANCE SHEETS

In thousands (except for share and per share data)

	December 31,

	2020	2019
	USD	
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 561	$ 2,156
Lease liability - current	43	36
Deferred revenues	334	469
Other accounts payable	331	610
Total current liabilities	1,269	3,271
NON-CURRENT LIABILITIES:		
Lease liability – non current	24	39
Deferred revenues	2,156	2,422
Total Long-term liabilities	2,180	2,461
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.25 par value - Authorized:1,000,000,000 shares as of December 31, 2020; 500,000,000 shares as of December 31, 2019; Issued and outstanding: 463,769,463 shares as of December 31, 2020; 120,652,683 shares as of December 31, 2019	33,036	8,225
Additional paid-in capital	97,380	103,401
Accumulated other comprehensive income	1,127	1,127
Accumulated deficit	(125,469)	(110,311)
Total equity	6,074	2,442
Total liabilities and equity	$ 9,523	$ 8,174

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands (except for share and per share data)

	Year ended December 31,	
2020	2019	2018
USD		

Revenues	$ 763	$ 2,032	$ 3,820
Research and development expenses	(11,951)	(10,976)	(6,075)
General and administrative expenses	(2,951)	(3,063)	(3,159)
Operating loss	(14,139)	(12,007)	(5,414)
Financial expense, net	(304)	(618)	(1,153)
Loss before taxes on income	(14,443)	(12,625)	(6,567)
Taxes on income	-	-	(4)
Net loss and other comprehensive loss	(14,443)	(12,625)	(6,571)
Basic and diluted net loss per share	$ (0.04)	$ (0.14)	$ (0.17)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	358,411,297	85,909,859	38,902,214

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, liver, inflammatory disease and COVID-19. The Company's lead drug candidate, Piclidenoson, is currently in a Phase III trial for psoriasis and a Phase II study in the treatment of moderate COVID-19. Can-Fite's liver drug, Namodenoson, is headed into a Phase III trial for hepatocellular carcinoma (HCC), the most common form of liver cancer, and successfully achieved its primary endpoint 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 1,500 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 impact of the recent outbreak of coronavirus; 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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