

Can-Fite BioPharma Ltd. (NYSE/CANF)

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BUY Rated; Piclidenoson in COVID

Can-Fite reported that the FDA has provided detailed comments regarding the prospective use of Piclidenoson to treat patients suffering from COVID-19. The FDA's response allows Can-Fite to proceed to the next step of formally submitting an IND for Piclidenoson in this indication. The planned Phase 2 trial will evaluate the efficacy and safety of Piclidenoson, when added to the current standard of care treatment, for COVID-19 infected patients with moderate-to-severe symptoms.

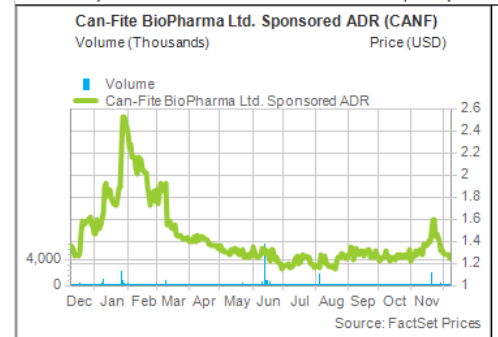
Investment Highlights

COVID 19. Can-Fite now, with FDA feedback, is planning to submit an IND application for Piclidenoson to be evaluated as a potential addition to the current standard of care treatment for COVID-19. Given the safety data base, we may see the drug jump into a Phase 2 Proof of Concept trial.

What might the trial look like? The pilot trial could be a randomized, open-label, 2-arm study of Piclidenoson plus standard supportive care, compared to standard supportive care alone, in n=40 hospitalized COVID-19 infected patients with moderate-to-severe symptomatic disease. Patients are to be randomized in a 1:1 ratio to one of the trial arms and treated for up to four weeks. Key efficacy measures include time to resolution of viral shedding, time to resolution of clinical symptoms, measures of respiratory function, need for ventilatory support, and overall mortality. Standard safety parameters will also be measured. Dr. Dror Diker, M.D., Head of Internal Medicine D at the Rabin Medical Center, is the Principal Investigator of the study.

ACROBAT & COMFORT – Both Are Half Way There. Piclidenoson is now in two pivotal Phase 3 studies (ACROBAT and COMFORT), and both are halfway plus enrolled. The ACROBAT study is a 24-week, 525-person four-arm (high and low dose versus MTX and placebo) study designed to establish the drug as non-inferior to Methotrexate (MTX) in newly diagnosed patients with moderate-to-severe RA. The primary endpoint of ACROBAT is a disease activity score (DAS) after 12 weeks of treatment in patients dosed with Piclidenoson compared to those dosed with MTX. In a Phase 2b study (N=79) with Piclidenoson given twice daily, 49% of patients achieved ACR20, 19% ACR50, and 11% ACR70. The scores are comparable to MTX but with a benign AE profile. Patients have been selected for the study based on overexpression of the A3AR biomarker. The study should complete enrollment this year, with data to follow in nine months.

Current Price	\$2.05		
Price Target	\$9.00		
Estimates	F2020A	F2021E	F2022E
Expenses (\$000s)	16,945	16,669	19,648
1Q March	4,474	3,834	4,519
2Q June	3,887	4,001	4,715
3Q September	4,211	4,334	5,108
4Q December	4,373	4,501	5,305
	F2019A	F2021E	F2022E
EPS (diluted)	(1.57)	(0.78)	(0.67)
1Q March	(0.47)	(0.20)	(0.15)
2Q June	(0.42)	(0.21)	(0.16)
3Q September	(0.46)	(0.22)	(0.17)
4Q December	(0.23)	(0.15)	(0.18)
EBITDA/Share	(\$0.15)	(\$0.16)	(\$1.08)
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$1.08	-	\$4.95
Shares Outstanding (mil.)	147.1		
Market Capitalization (mil.)	\$301.5		
Enterprise Value (mil.)	\$9.3		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	15.1		
Average Three Months Trading Volume (M)	1.5		
Insider Ownership	9.1%		
Institutional Ownership	8.2%		
Short interest (mil.)	0.1%		
Dividend / Yield	\$0.00/0.0%		



The COMFORT pivotal trial too. The study is designed to evaluate the efficacy and safety of daily Piclidenoson, administered orally, compared to Apremilast (Otezla) and placebo in 407 patients with moderate-to-severe plaque psoriasis. The study is being conducted in five countries in Europe, Israel, and Canada. The primary endpoint is to be based on the percent of patients which achieve a PASI 75 score at week 16 vs. placebo. The secondary endpoints are to include non-inferiority vs. Otezla at week 32. Psoriasis alone is estimated to be a \$9B market.

So, it's ACROBAT & COMFORT. Not one, but two Phase 3 trials with Piclidenoson. ACROBAT in Rheumatoid Arthritis and COMFORT in Psoriasis. Both hold great promise as alternative therapies with what appears to be a more favorable side-effects profile.

Namodenoson in Liver Cancer – Pivotal is Next. The FDA has agreed with Can-Fite's proposed pivotal Phase 3 trial design. The study protocol and registration plan have also been submitted to the European Medicines Agency (EMA). Namodenoson is currently being used to treat liver cancer patients in a compassionate use program in Israel, which has enrolled seven patients. In addition, two patients who were enrolled in the Company's former Phase 2 study, who responded well to the drug, are continuing treatment. Those two advanced liver cancer patients have reached an overall survival of over 2.5 years while being treated with Namodenoson.

Funded Through Catalysts – Capital Raised. We had assumed in our model (and continue to assume) multiple raises. Can-Fite sold 3.3M shares at \$1.50 per unit (an ADR and a warrant). In addition, a warrant exercise with several accredited investors brought into the Company an additional \$2.4M in capital (Jan. 9th 2020).

Valuation. We model the respective indications, Piclidenoson in RA and Psoriasis, Namodenoson in HCC, and NAFLD. We apply a probability of success in these patient-based models. These metrics then flow into our valuation models. For Can-Fite, we apply a 30% discount rate, which is in addition to our therapeutic probability of success rate. We select 30% as the Company is not yet profitable, and most of the products are still dependent on the outcome of the clinical trial. Our valuation conclusion is an equally-weighted average of our FCFF, EPS, and sum-of-the-parts analysis. We use a fully diluted end-year share count and assume multiple raises. The conclusion of this method is a \$9.00 price target.

Risk to our thesis, include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.

Valuation. Our valuation is based on our therapeutic models, which include probability of success factors for each product and each model. For Piclidenoson, we use a probability of success of just 50% in RA and Psoriasis. The same is true for Namodenoson, except that here the mechanism of action is new, and the data is based on Phase 2 trials, and the disease conditions can be heterogeneous. For example, in HCC, there are often multiple mechanisms of action behind cancer's growth. Blocking one path often results in the cancer adapting to leverage a different pathway. In NASH, we assume just a 10% probability as the current study is exploratory. The result of these models then drives the Company's income statement. The valuation conclusion is an equally-weighted average of our FCFF, EPS, and sum-of-the-parts analysis, discounted at a rate of 30% to account for the risks of development and rounded to the nearest whole number. For companies that are well established with mature products and revenues, we typically use a 10% risk rate. For companies in the early stages of product commercialization, we typically choose a higher risk rate of 15%. For Can-Fite, we use our maximum discount rate of 30% as the Company does not yet have an approved therapeutic product.

Can-Fite has received approximately \$14 million in upfront and milestone payments from multiple partners including Kwang Dong (Korea: A009290; not rated) to develop and commercialize Piclidenoson for RA in Korea, Cipher (TSX: CPH; not rated), Chong Kun Dang (Korea: 185750; not rated) for Namodenoson for HCC and most recently Gebro Pharma (private) for Piclidenoson in RA and Psoriasis in Spain and Austria. We expect to see additional and larger partnership deals (such as the one recently announced with Kyongbo), which represent a source of non-dilutive capital to the Company.

In our model, we assume multiple raises. For purposes of our model, we now assume 40M shares are outstanding by 2030. We assume Can-Fite is likely to be back in the markets raising capital this year and for the next several years. We are hopeful that positive data from ACROBAT study in RA and the COMFORT trial in Psoriasis will set the stage for a rise in valuation.

Exhibit 5. Discounted Free-Cash-Flow Model

Average		9
Price Target		11
Year		2020

DCF Valuation Using FCF (mln):

units ('000)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(15,998)	(16,669)	(19,648)	(23,881)	112,405	298,356	386,317	484,325	562,494	626,365	694,472
Tax Rate	0%	0%	0%	0%	5%	8%	12%	25%	30%	32%	34%
EBIT (1-t)	(15,998)	(16,669)	(19,648)	(23,881)	106,785	274,488	339,959	363,244	393,746	425,928	458,351
CapEx	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-
FCF	(15,998)	(16,669)	(19,648)	(23,881)	106,785	274,488	339,959	363,244	393,746	425,928	458,351
PV of FCF	(15,998)	(12,823)	(11,626)	(10,870)	37,388	73,928	70,431	57,889	48,269	40,165	33,248
Discount Rate	30%										
Long Term Growth Rate	1%										
Cash Flow	1,596,327										
Terminal Value YE2030	115,795										
NPV	425,797										
NPV-Debt											
Shares out ('000)	40,358	2030E									
NPV Per Share	10.6										

Source: Dawson James

Exhibit 6. EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	5
Discount Factor	30%
Selected Year EPS	17.21
NPV	6.24

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	2	21	13	9	6	4	2
	5	53	33	21	14	9	6
	10	106	66	43	28	18	12
	15	158	100	64	42	28	19
	20	211	133	85	56	37	25
	25	264	166	106	69	46	31
	30	317	199	128	83	55	37
	35	370	232	149	97	65	44

Source: Dawson James

Exhibit 7. Sum-of-the-Parts Model

	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (M)	NPV
Piclidenoson (RA) U.S.	1%	30%	4	50%	\$227	\$783
NPV						\$2.4
Piclidenoson (RA) EU	1%	30%	5	50%	\$757	\$2,612
NPV						\$6.1
Piclidenoson (Psoriasis) U.S.	1%	30%	4	50%	\$212	\$732
NPV						\$2.2
Piclidenoson (Psoriasis) EU	1%	30%	5	50%	\$282	\$971
NPV						\$2.3
Namodenoson (Liver Cancer) U.S.	1%	30%	5	50%	\$63	\$216
NPV						\$0.5
Namodenoson (Liver Cancer) EU	1%	30%	5	50%	\$87	\$302
NPV						\$0.7
Namodenoson (NAFLD/NASAH) U.S.	1%	30%	6	50%	\$366	\$1,263
NPV						\$2.3
Namodenoson (NAFLD/NASAH) EU	1%	30%	7	50%	\$220	\$758
NPV						\$1.0
Pipeline	1%	30%	7	0%	\$50	\$172
NPV						\$0.0
Net Margin						70%
MM Shrs OS (2030E)						40
Total						\$9.1

Source: Dawson James

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Can-Fite are as follows:

Financial risk. The Company may need to raise capital in the marketplace, and there can be no assurances that the Company will be able to successfully raise capital and or do so on favorable terms.

Clinical and regulatory risk. Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

Commercial risk. There are no assurances that the Company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

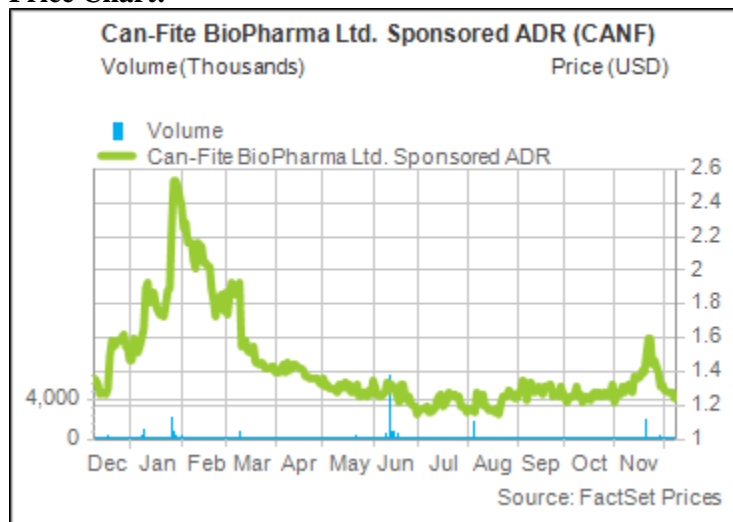
Legal and intellectual property risk. The Company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the Company may infringe on third party's patents.

Companies mentioned in this report:

Kwang Dong (Korea: A009290; Not rated)
 Kyongbo Pharm (Korea XKRX; Not Rated)
 Cipher (TSX: CPH; Not rated)
 Chong Kun Dang (Korea: 185750; Not rated)
 Gebro Pharma (private)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

Initiated – Buy – December 12, 2018 – Price Target \$7
 Update – Buy – March 26, 2019 – Price Target \$6
 Update – Buy – May 21, 2019 – Price Target \$9 (adjusted down after reverse stock split).
 Update – Buy – August 7, 2019 – Price Target \$9
 Update – Buy – September 11, 2019 – Price Target \$9
 Update – Buy – September 18, 2019 – Price Target \$9
 Update – Buy – September 23, 2019 – Price Target \$9
 Update – Buy – October 15, 2019 – Price Target \$9
 Update – Buy – October 31, 2019 – Price Target \$9
 Update – Buy – November 4, 2019 – Price Target \$9
 Update – Buy – December 2, 2019 – Price Target \$9
 Update – Buy – December 11, 2019 – Price Target \$9
 Update – Buy – February 3, 2020 – Price Target \$9
 Update – Buy – February 19, 2020 – Price Target \$9
 Update – Buy – March 5, 2020 – Price Target \$9
 Update – Buy – April 13, 2020 – Price Target \$9
 Update – Buy – April 20, 2020 – Price Target \$9
 Update – Buy – May 19, 2020 – Price Target \$9
 Update – Buy – June 1, 2020 – Price Target \$9
 Update – Buy – June 9, 2020 – Price Target \$9

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- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	88%	3	14%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	25	100%	4	16%

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