

Can-Fite BioPharma Ltd. (NYSE/CANF)

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BUY Rated: COMFORT Advances (Psoriasis) while Acrobat Falls (RA Stops)

The Independent Data Monitoring Committee (IDMC) conducted a pre-planned interim analysis of the Company's Phase 3 Comfort trial of Piclidenoson to treat psoriasis. It is recommended to continue with this psoriasis study. A separate IDMC for the pre-planned interim analysis of the Acrobat Rheumatoid Arthritis (RA) Phase 3 study advised not to continue this study. The Company plans to undertake a detailed analysis of the RA study's data and decide on the next steps.

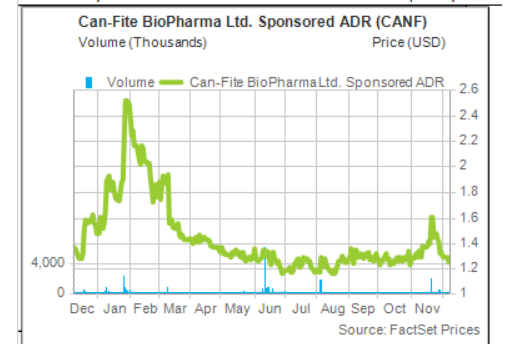
Investment Highlights

COMFORT Continues ... An Independent Data Monitoring Committee recommended the Phase 3 psoriasis study continue. The IDMC also recommended that one of the dosing groups be dropped. The committee advised "no change" to the sample size, which we view as positive. Recall that 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 who 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.

ACROBAT stops. The IDMC has recommended the study be stopped. This study is a 24-week, 525-person four-arm (high and low dose versus MTX and placebo) trial 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 the overexpression of the A3AR biomarker. Management is evaluating next steps. We had assumed just a 50% probability of success, for now, we remove RA from our model, which lowers our target valuation from \$7.00 to \$5.00.

Piclidenoson as a therapeutic in COVID. The trial is to assess efficacy through standard measures of clinical and respiratory status at Day 29, including the proportion of patients alive and free of respiratory failure, as well as the proportion discharged home without need for supplemental oxygen. Safety and pharmacokinetic data will also be captured.

Current Price				\$1.75
Price Target				\$5.00
Estimates	F2020E	F2021E	F2022E	
Expenses (\$000s)	17,093	16,669	19,648	
1Q March	4,474	3,834	4,519	
2Q June	4,035	4,001	4,715	
3Q September	4,211	4,334	5,108	
4Q December	4,373	4,501	5,305	
	F2020E	F2021E	F2022E	
EPS (diluted)	(1.12)	(0.57)	(0.53)	
1Q March	(0.47)	(0.14)	(0.12)	
2Q June	(0.24)	(0.15)	(0.13)	
3Q September	(0.25)	(0.16)	(0.14)	
4Q December	(0.16)	(0.12)	(0.14)	
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.)				15.4
Market Capitalization (mil.)				\$27.0
Enterprise Value (mil.)				\$16.5
Debt to Capital				0.0%
Book Value/Share				\$4.52
Price/Book				15.1
Average Three Months Trading Volume (M)				0.8
Insider Ownership				5.4%
Institutional Ownership				8.9%
Short interest (mil.)				2.2%
Dividend / Yield				\$0.00/0.0%



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.

Valuation. We have removed Piclidenoson in RA but maintain it in 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 \$5.00 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.

Product Modeling Assumptions

1. We assume the program in RA does not continue but Psoriasis does to a second pivotal trial. If we assume a similar size, cost, and time for the studies, it suggests we could see U.S. top line data in a year from the current trial.
2. We assume Can-Fite may partner Piclidenoson (and Namodenoson). For the purpose of our model, we assume a sliding scale royalty at a base of 25% but rising to 30% based on sales levels. In accordance with this assumption, we only moderately increase G&A expenses as the Company is not likely to build a salesforce in this scenario.
3. We assume pricing of \$5,000 in the U.S. and \$3,000 in Europe with 2% year on year increases for Piclidenoson in Psoriasis, and the target population is assumed to be high A₃AR expressers.
4. A probability success factor of 50% to our models for Psoriasis.
5. We now assume Namodenoson is approved and launches (U.S. and Europe), for late-stage liver cancer in 2024.
6. We assume Namodenoson pricing of \$50,000 in the U.S. and \$35,000 in Europe with a 2% y/y increase.
7. A probability success factor of 50% is applied to our HCC model-based, which is based on Phase 2 data.
8. A probability success factor of 10% to our U.S. and EU models for NAFLD/NASH as the current Phase 2 study is exploratory, and the clinical development pathway for this indication is long and expensive and may require a partner to pay development costs. As such, we believe it's prudent to heavily discount the indication.
9. We do not include CF 602 for the ED indication in our model as the product is still in early stages of testing. We assume a partner is needed to move the project into the clinic.
10. We do not include any estimates for COVID.

Exhibit 1. U.S. Market Model for Psoriasis

Piclidenoson - CF101 (US)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Psoriasis incidence	7,178,760	7,322,335	7,468,782	7,618,158	7,770,521	7,925,931	8,084,450	8,246,139	8,411,061	8,579,283	8,750,868	8,925,886	9,104,403
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Plaque psoriasis (80%)	5,743,008	5,857,868	5,975,026	6,094,526	6,216,417	6,340,745	6,467,560	6,596,911	6,728,849	6,863,426	7,000,695	7,140,709	7,283,523
Moderate to severe plaque psoriasis (17%)	976,311	995,838	1,015,754	1,036,069	1,056,791	1,077,927	1,099,485	1,121,475	1,143,904	1,166,782	1,190,118	1,213,920	1,238,199
Patients seeking treatment (84%)	820,102	836,504	853,234	870,298	887,704	905,458	923,568	942,039	960,880	980,007	999,699	1,019,693	1,040,087
Market Penetration						0.0%	3.0%	6.0%	7.0%	8.0%	9.0%	10.0%	11.0%
Patients receiving CF101						-	27,707	56,522	67,262	78,408	89,973	101,969	114,410
Annual cost of treatment						\$ 5,000	\$ 5,100	\$ 5,202	\$ 5,306	\$ 5,412	\$ 5,520	\$ 5,631	\$ 5,743
Increase in Price						2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)						\$ -	\$ 141,306	\$ 294,029	\$ 356,893	\$ 424,356	\$ 496,687	\$ 574,170	\$ 657,103
Probability of Success						50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						\$ -	\$ 70,653	\$ 147,015	\$ 178,446	\$ 212,178	\$ 248,343	\$ 287,085	\$ 328,552

Source: Dawson James estimates, company reports

Exhibit 2. EU Market Model for Psoriasis

Piclidenoson - CF101 (EU)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Psoriasis incidence	11,548,440	11,779,409	12,014,907	12,255,297	12,500,403	12,750,411	13,005,419	13,265,528	13,530,838	13,801,455	14,077,484	14,359,034	14,646,214
Increase in incidence	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Plaque psoriasis (80%)	9,238,752	9,423,527	9,611,998	9,804,238	10,000,322	10,200,329	10,404,335	10,612,422	10,824,670	11,041,164	11,261,987	11,487,227	11,716,971
Moderate to severe plaque psoriasis (17%)	1,570,588	1,602,000	1,634,040	1,666,720	1,700,055	1,734,056	1,768,737	1,804,112	1,840,194	1,876,998	1,914,538	1,952,829	1,991,885
Patients seeking treatment (84%)	1,319,294	1,345,680	1,372,593	1,400,045	1,428,046	1,456,607	1,485,739	1,515,454	1,545,763	1,576,678	1,608,212	1,640,376	1,673,184
Market Penetration						0.0%	2.0%	9.0%	10.0%	11.0%	12.0%	13.0%	14.0%
Patients receiving CF101						-	29,715	136,391	154,576	173,435	192,985	213,249	234,246
Price of treatment						\$ 3,000	\$ 3,060	\$ 3,121	\$ 3,184	\$ 3,247	\$ 3,312	\$ 3,378	\$ 3,446
Increase in Price						2%	2%	2%	2%	2%	2%	2%	2%
Revenue ('000)						\$ -	\$ 90,927	\$ 425,703	\$ 492,113	\$ 563,194	\$ 639,214	\$ 720,459	\$ 807,224
Probability of Success						50%	50%	50%	50%	50%	50%	50%	50%
Total Revenue ('000)						\$ -	\$ 45,464	\$ 212,852	\$ 246,056	\$ 281,597	\$ 319,607	\$ 360,229	\$ 403,612

Source: Dawson James estimates, company reports

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.

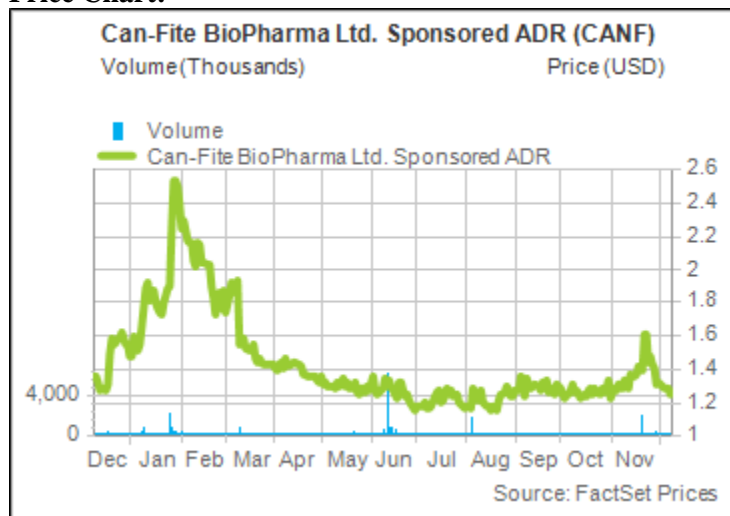
Commercial risk. There are no assurances that the Company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

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 parties' patents.

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – December 13, 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
- PT Change – Buy – June 10, 2020 – Price Target lowered from \$9 to \$7.0
- Update – Buy – June 30, 2020 – Price Target \$7
- Update – Buy – July 30, 2020 – Price Target \$7
- Update – Buy – August 31, 2020 – Price Target \$7
- PT Change – Buy – October 6, 2020 – Price Target \$5

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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.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	85%	4	17%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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