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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Can-Fite BioPharma Ltd. (NYSE/CANF)

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Jason Kolbert

Managing Director & Senior Analyst

jkolbert@dawsonjames.com

BUY: Going Pivotal – Two US-Based Psoriasis Trials Including Adolescents

Can-Fite announced that it received feedback and advice from the FDA with respect to Piclidenoson development plans in the U.S. The company is now planning to conduct two pivotal trials (in parallel) which can be used for both US and EU approval.

Investment Highlights:

Piclidenoson Plan: Can-Fite announced that the company has submitted registration plans for both the EMA and FDA and received feedback from both agencies - the “go-ahead”. These plans include final efficacy and safety results from Can-Fite’s COMFORT Phase III study and the protocol for the Company’s upcoming pivotal trial together with a request for registration advice from the regulators. Current chemistry, manufacturing, and controls (CMC), nonclinical data, and human pharmacokinetic data are also included. Recall that Can-Fite reported topline results from the COMFORT study which met its primary endpoint, demonstrating a statistically significant improvement over placebo in psoriasis patients and an excellent safety profile for Piclidenoson. The data point towards a better safety profile for Piclidenoson as compared to Otezla, the leading oral therapy for psoriasis on the market today, as Otezla induced: 1) gastro-intestinal adverse events in 6% of patients compared with 1% in patients treated with placebo or Piclidenoson; and 2) 9.9% nervous system disorders in the Otezla vs. 0.7% in the Piclidenoson treated patients.

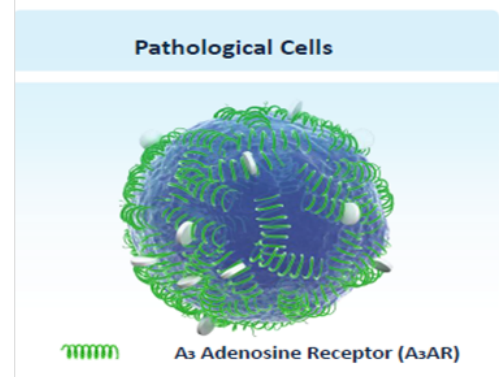
Green Light from EMA for a Pivotal Phase 3 Psoriasis Study—The European Medicines Agency (EMA) gave Can-Fite a positive opinion on its registration plan for a pivotal Phase 3 clinical trial for Piclidenoson in the treatment of moderate to severe psoriasis. The pivotal study and the safety of the 3 mg twice daily dose of Piclidenoson are accepted by the agency.

Can-Fite has submitted a comparable data package to the U.S. Food and Drug Administration (FDA) and has now received advice on how to move forward. The trials, two in parallel, may include adolescents (based on the established safety profile).

Valuation. We evaluate Piclidenoson in Psoriasis, Namodenoson in HCC, and NAFLD, we do not include pancreatic cancer (yet). We apply a probability of success factor in these patient-based models. These metrics then flow into our valuation models. For Can-Fite, we use a 30% discount rate (in addition to the risk rate), as Can-Fite is not yet profitable, and most of the products are still dependent on the outcome of the clinical trials. Our valuation conclusion is an equally weighted average of our FCFE, EPS, and sum-of-the-parts analysis. We use a projected fully diluted end-year share count and assume multiple raises which results in our model.

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

Current Price	\$3.02
Price Target	\$6.00



Source: Can-Fite

Stock Data			
52-Week Range	\$1.52	-	\$10.30
Shares Outstanding (mil.)	4.1		
Market Capitalization (mil.)	\$12.3		
Enterprise Value (mil.)	\$0.1		
Debt to Capital	0.0%		
Book Value/Share	\$45.18		
Price/Book	3.7		
Average Three Months Trading Volume (M)	0.0		
Insider Ownership	-		
Institutional Ownership	9.4%		
Short interest (mil.)	1.5%		
Dividend / Yield	\$0.00/0.0%		

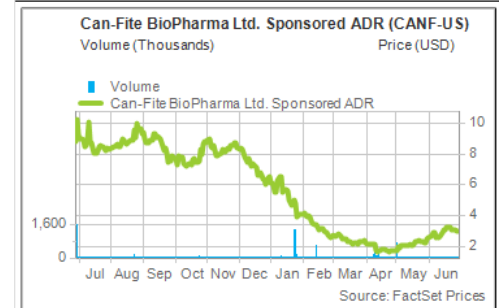


Exhibit 1. Income Statement

Can-Fite Biopharma: Income Statement (\$'000)																
: YE December 31	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:	2,032	763	853	810	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Rheumatoid Arthritis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Rheumatoid Arthritis EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Psoriasis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	53,044	110,375	172,251	238,947
Piclidenoson (CF-101), Psoriasis EU	-	-	-	-	-	-	-	-	-	-	-	-	51,199	106,536	166,260	230,635
Namodenoson HCC U.S.	-	-	-	-	-	-	-	-	-	-	8,261	17,189	26,825	37,212	48,394	60,419
Namodenoson HCC EU	-	-	-	-	-	-	-	-	-	-	11,543	24,019	37,484	51,998	67,624	84,427
Namodenoson NASH/NAFLD U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Namodenoson NASH/NAFLD EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Product Sales	2,032	763	853	810	-	-	-	-	-	-	19,804	41,208	168,553	306,121	454,529	614,428
Milestone From Gebro Holdings	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Rheumatoid Arthritis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Rheumatoid Arthritis EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenoson (CF-101), Psoriasis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	13,261	27,594	43,063	59,737
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	26%	26%	26%	26%
Piclidenoson (CF-101), Psoriasis EU	-	-	-	-	-	-	-	-	-	-	-	-	13,261	27,594	43,063	59,737
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	26%	26%	26%	26%
Namodenoson HCC U.S.	-	-	-	-	-	-	-	-	-	-	2,065	4,297	6,706	9,303	12,099	15,105
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	25%	25%	25%	25%	25%	25%
Namodenoson HCC EU	-	-	-	-	-	-	-	-	-	-	2,886	6,485	10,121	14,040	18,258	22,795
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	25%	27%	27%	27%	27%	27%
Namodenoson NASH/NAFLD U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Namodenoson NASH/NAFLD EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total royalties, collaborative revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	2,032	763	853	810	196	-	-	-	196	-	4,951	10,782	43,349	78,530	116,482	157,373
Expenses:																
Partnership Costs including COGS	-	-	-	-	-	-	-	-	-	-	990	2,060	8,428	15,306	22,726	30,721
Research and Development	10,976	11,951	9,850	7,763	2,061	1,900	2,059	2,138	7,918	8,077	8,238	8,403	8,571	8,742	8,917	9,096
General and Administrative	3,059	2,951	3,845	3,143	847	2,880	3,120	3,240	12,000	12,600	13,230	13,892	14,586	15,315	16,081	16,885
Total Expenses	14,035	14,902	13,695	10,906	2,908	4,780	5,179	5,378	19,918	20,677	22,458	24,355	31,585	39,364	47,725	56,702
Operating Income (Loss)	(12,003)	(14,139)	(12,842)	(10,096)	(2,712)	(4,780)	(5,179)	(5,378)	(19,722)	(20,677)	(17,507)	(13,572)	11,765	39,166	68,758	100,671
Finance expenses	693	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Finance income	3,109	(304)	227	(77)	162	-	-	-	-	-	-	-	-	-	-	-
Total Other Income	2,416	(304)	227	(77)	162	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(9,587)	(13,835)	(12,615)	(10,173)	(2,550)	(4,780)	(5,179)	(5,378)	(19,722)	(20,677)	(17,507)	(13,572)	11,765	39,166	68,758	100,671
Taxes on income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Taxes	-	(715)	(2,590)	-	-	-	-	-	-	(1,034)	(1,401)	-	588	3,917	11,001	25,168
Remeasurement loss from defined benefit plans	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax Rate	-	-	-	-	-	-	-	-	-	0%	0%	0%	5%	10%	16%	25%
GAAP Net Income (Loss)	(9,587)	(14,443)	(12,615)	(10,173)	(2,550)	(4,780)	(5,179)	(5,378)	(19,722)	(20,677)	(17,507)	(13,572)	11,176	35,250	57,756	75,503
GAAP-EPS	(1.77)	(1.02)	(0.58)	(0.28)	(0.31)	(0.42)	(0.46)	(0.47)	(1.87)	(1.30)	(1.00)	(0.78)	0.64	2.00	3.26	4.25
GAAP-EPS (Dil)	(1.35)	(0.48)	(0.33)	(0.13)	(0.43)	(0.40)	(0.43)	(0.45)	(1.88)	(1.15)	(0.87)	(0.67)	0.55	1.73	2.83	3.68
Wgtd Avg ADR Shrs (Bas) - '000s	5,833	17,191	21,416	37,202	8,298	11,306	11,317	11,329	10,562	15,862	17,430	17,499	17,570	17,640	17,711	17,781
Wgtd Avg ADR Shrs (Dil) - '000s	8,910	29,866	38,014	80,120	6,000	12,006	12,018	12,030	10,514	18,026	20,090	20,171	20,251	20,333	20,414	20,496

Source: Dawson James Securities 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.

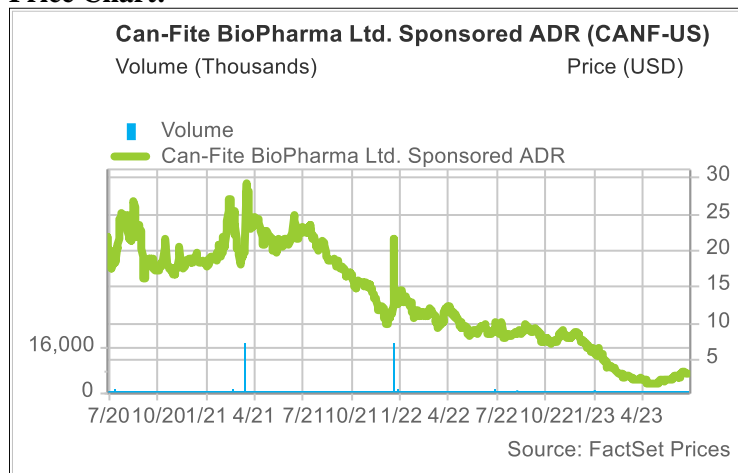
Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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.

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
Update – Buy – November 16, 2020 – Price Target \$5
Update – Buy – December 1, 2020 – Price Target \$5
Update – Buy – January 25, 2021 – Price Target \$5
Update – Buy – February 23, 2021 – Price Target \$5
Update – Buy – March 5, 2021 – Price Target \$5
Update – Buy – March 29, 2021 – Price Target \$5
Update – Buy – April 22, 2021 – Price Target \$5
Update – Buy – April 29, 2021 – Price Target \$5
Update – Buy – May 27, 2021 – Price Target \$5
Update – Buy – June 4, 2021 – Price Target \$5
Update – Buy – July 8, 2021 – Price Target \$5
Update – Buy – August 27, 2021 – Price Target \$5
Update – Buy – December 7, 2021 – Price Target \$5
Update – Buy – December 20, 2021 – Price Target \$5
Update – Buy – January 5, 2022 – Price Target \$5
Update – Buy – January 31, 2022 – Price Target \$5
Update – Buy – March 8, 2022 – Price Target \$5
Update – Buy – March 25, 2022 – Price Target \$5
Update – Buy – May 26, 2022 – Price Target \$5
Update – Buy – June 29, 2022 – Price Target \$5
Update – Buy – July 11, 2022 – Price Target \$5
Update – Buy – August 22, 2022 – Price Target \$5
Update – Buy – August 23, 2022 – Price Target \$5
Update – Buy – September 1, 2022 – Price Target \$5
Update – Buy – September 12, 2022 – Price Target \$5
Update – Buy – September 21, 2022 – Price Target \$5
Update – Buy – October 14, 2022 – Price Target \$5
Update – Buy – October 25, 2022 – Price Target \$5
Update – Buy – November 29, 2022 – Price Target \$5
Price Target Change – Buy – December 12, 2022 – Price Target \$8
Update – Buy – December 28, 2022 – Price Target \$8
Rating Change – Buy to Neutral – January 3, 2023 – Price Target NA
Update – Neutral – January 12, 2023 – Price Target NA
Update – Neutral – March 14, 2023 – Price Target NA
Update – Neutral – April 10, 2023 – Price Target NA
Rating Change – Neutral to Buy – May 1, 2023 – Price Target \$6.0
Update – Buy – May 30, 2023 – Price Target \$6.0
Update – Buy – June 1, 2023 – Price Target \$6.0
Update – Buy – June 15, 2023 – Price Target \$6.0
Update – Buy – June 29, 2023 – Price Target \$6.0

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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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Current as of 22-Jun-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	2	5.50%
Market Perform (Neutral)	10	28%	2	5.50%
Market Underperform (Sell)	0	0%	0	0.00%
Total	36	100%	4	11.00%

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