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Can-Fite BioPharma Ltd. (NYSE/CANF)

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BUY-Rated: Expected Milestones

Can-Fite in a letter to shareholders outlined the milestones ahead for the year.

Investment Highlights

COMFORT-Plaque Psoriasis: Topline Phase 3 Psoriasis Data Expected Q122

- Comfort Phase 3 study of Piclidenoson enrolled and treated approximately 400 patients with moderate to severe plaque psoriasis. In Q1 Can-Fite expects to announce results from the first 16 weeks of treatment, with the primary endpoint of the study being a statistically significant improvement in achieving a PASI score of 75 in Piclidenoson treated patients vs. placebo.
- Later in 2022 the company expects to announce the study's secondary endpoint at 32 weeks of treatment which is non-inferiority of Piclidenoson vs. Otezla. The study has four treatment arms: Piclidenoson 2 mg, Piclidenoson 3 mg, Otezla, and placebo.

Namodenoson in NASH: Phase 2b study: NASH Study Expected to Commence Patient Enrollment in Q122

- The study will enroll 140 patients with biopsy-confirmed NASH with a primary endpoint to evaluate the efficacy of Namodenoson as compared to placebo, as determined by a histological endpoint. Patients will be randomly assigned in a 2:1 ratio to oral doses of Namodenoson 25 mg or placebo every 12 hours for 36 weeks.

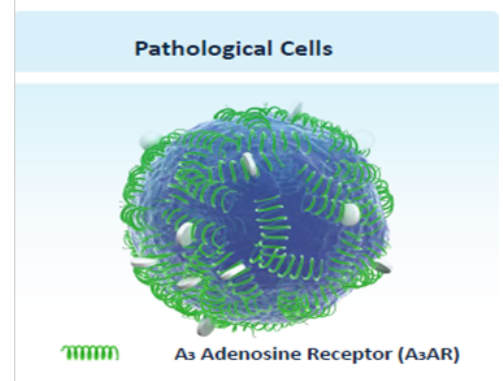
Liver Cancer: Patient Enrollment Expected to Commence in the Phase 3 Study H122

- In December, we announced that a prior Phase II liver cancer study patient who continues to be treated with Namodenoson has survived five years and cleared all cancer lesions. We see this as a very positive sign as we expect to commence enrollment in Q1 of 2022.
- Approximately 450 patients diagnosed with hepatocellular carcinoma (HCC) and underlying Child Pugh B7 (CPB7) who have not responded to other approved therapies will be enrolled through clinical sites worldwide. Patients will be randomized to oral treatment with either 25 mg Namodenoson or matching placebo given twice daily. The primary efficacy endpoint of the trial is overall survival.
- An interim analysis is set once 50% of patients are enrolled.

Valuation. We evaluate Piclidenoson 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 use a 30% discount rate and apply a therapeutic probability of success rate (in that model). Our risk rate in our financial models is 30% 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 FCFF, EPS, and sum-of-the-parts analysis. We use a projected fully diluted end-year share count and assume multiple raises. The conclusion of this method is a \$5.00 price target.

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

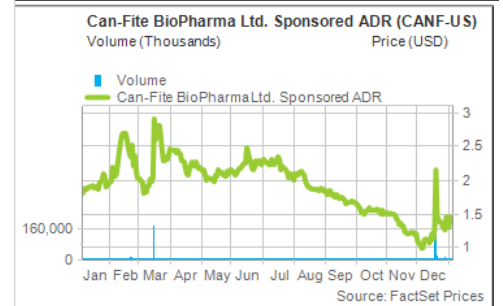
Current Price	\$1.39
Price Target	\$5.00



Source: Can-Fite

Stock Data

52-Week Range	\$0.94	-	\$4.39
Shares Outstanding (mil.)	27.2		
Market Capitalization (mil.)	\$37.8		
Enterprise Value (mil.)	\$15.8		
Debt to Capital	0.0%		
Book Value/Share	\$4.52		
Price/Book	4.5		
Average Three Months Trading Volume (M)	0.1		
Insider Ownership	0.1%		
Institutional Ownership	7.3%		
Short interest (mil.)	1.2%		
Dividend / Yield	\$0.00/0.0%		



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 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. Product Market Models

Table with columns for Product (Piclidenoson - CF101 (US), Piclidenoson - CF101 (EU), Namodenoson - CF102 (US), Namodenoson - CF102 (EU-5)) and years 2018E through 2030E. Rows include metrics like Incidence, Market Penetration, Price of treatment, Revenue, and Total Revenue (000).

Source: Dawson James Securities estimates, company reports

Exhibit 2. Income Statement

Can-Fite Biopharma.: Income Statement (\$'000)																
.. YE December 31	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:	2,032	763	148	250	252	-	650	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Rheumatoid Arthritis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Rheumatoid Arthritis EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Psoriasis U.S.	-	-	-	-	-	-	-	-	-	91,849	191,119	231,980	275,831	322,846	373,211	427,117
Piclidenson (CF-101), Psoriasis EU	-	-	-	-	-	-	-	-	-	59,103	276,707	319,873	366,076	415,489	468,298	524,696
Namodenoson HCC U.S.	-	-	-	-	-	-	-	-	-	7,940	41,304	51,567	62,592	74,424	87,110	100,699
Namodenoson HCC EU	-	-	-	-	-	-	-	-	-	11,095	57,716	72,057	87,463	103,996	121,722	140,711
Namodenoson NASH/NAFLD U.S.	-	-	-	-	-	-	-	-	-	81,284	169,135	263,953	366,155	380,948	396,338	412,350
Namodenoson NASH/NAFLD EU	-	-	-	-	-	-	-	-	-	-	67,654	140,775	219,693	304,758	317,071	329,880
Total Product Sales	2,032	763	148	250	252	-	650	-	-	158,892	509,130	603,421	704,499	812,760	928,618	1,052,512
Milestone From Gebro Holdings	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Rheumatoid Arthritis U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Rheumatoid Arthritis EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Piclidenson (CF-101), Psoriasis U.S.	-	-	-	-	-	-	-	-	-	22,962	47,780	57,995	68,958	80,712	93,303	106,779
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	39%	17%	18%	19%	19%	20%	20%
Piclidenson (CF-101), Psoriasis EU	-	-	-	-	-	-	-	-	-	22,962	47,780	57,995	68,958	80,712	93,303	106,779
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	39%	17%	18%	19%	19%	20%	20%
Namodenoson HCC U.S.	-	-	-	-	-	-	-	-	-	1,985	10,326	12,892	15,648	18,606	21,777	25,175
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	25%	25%	25%	25%	25%	25%	25%
Namodenoson HCC EU	-	-	-	-	-	-	-	-	-	2,774	14,429	18,014	23,615	28,079	32,865	37,992
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	25%	25%	25%	27%	27%	27%	27%
Namodenoson NASH/NAFLD U.S.	-	-	-	-	-	-	-	-	-	20,321	42,284	65,988	93,223	96,989	100,908	104,984
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	25%	25%	25%	25%	25%	25%	25%
Namodenoson NASH/NAFLD EU	-	-	-	-	-	-	-	-	-	-	16,914	35,194	54,923	76,190	79,268	82,470
Royalty Rate from Global Partnership	-	-	-	-	-	-	-	-	-	-	25%	25%	25%	25%	25%	25%
Total royalties, collaborative revenue	-	-	-	-	-	-	-	-	-	71,004	179,512	248,078	325,325	381,287	421,423	464,180
Total Revenue	2,032	763	148	250	252	-	650	-	-	71,004	179,512	248,078	325,325	381,287	421,423	464,180
Expenses:																
Partnership Costs including COGS	-	-	-	-	-	-	-	-	-	7,945	25,457	30,171	35,225	40,638	46,431	52,626
Research and Development	10,976	11,951	1,303	2,507	2,940	-	6,750	6,885	7,023	7,163	7,306	7,453	7,602	7,754	7,909	8,067
General and Administrative	3,059	2,951	1,016	876	818	-	2,710	8,000	12,000	12,600	13,230	13,892	14,586	15,315	16,081	16,885
Total Expenses	14,035	14,902	2,319	3,383	3,758	-	9,460	14,885	19,023	27,708	45,993	51,515	57,413	63,707	70,421	77,578
Operating Income (Loss)	(12,003)	(14,139)	(2,171)	(3,133)	(3,506)	-	(8,810)	(14,885)	(19,023)	43,296	133,519	196,563	267,913	317,580	351,002	386,602
Finance expenses	693	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Finance income	3,109	(304)	293	(86)	103	-	310	-	-	-	-	-	-	-	-	-
Total Other Income	2,416	(304)	293	(86)	103	-	310	-	-	-	-	-	-	-	-	-
Pretax Income	(9,587)	(13,835)	(1,878)	(3,047)	(3,609)	-	(9,120)	(14,885)	(19,023)	43,296	133,519	196,563	267,913	317,580	351,002	386,602
Taxes on income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Adjustments arising from translating financial statements of foreign operations	-	(715)	-	-	-	-	-	-	-	2,165	10,682	23,588	66,978	95,274	112,321	131,445
Remeasurement loss from defined benefit plans	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax Rate	-	-	-	-	-	-	-	-	-	5%	8%	12%	25%	30%	32%	34%
GAAP Net Income (Loss)	(9,587)	(14,443)	(1,878)	(3,047)	(3,609)	-	(9,120)	(14,885)	(19,023)	43,296	133,519	196,563	267,913	317,580	351,002	386,602
Total comprehensive loss	(9,587)	(15,158)	(1,878)	(3,047)	(3,609)	-	(9,120)	(14,885)	(19,023)	45,461	122,838	172,976	200,934	222,306	238,682	255,157
GAAP-EPS	(1.77)	(1.02)	(0.11)	(0.16)	(0.16)	-	(0.43)	(0.30)	(0.38)	0.86	2.63	3.86	5.24	6.19	6.82	7.48
GAAP-EPS (Dil)	(1.35)	(0.48)	(0.06)	(0.05)	(0.16)	-	(0.21)	(0.19)	(0.24)	0.54	1.65	2.41	3.28	3.87	4.26	4.67
Wgtd Avg ADR Shrs (Bas) - '000s	5,833	17,191	17,191	19,091	22,192	30,000	22,118	50,075	50,276	50,477	50,679	50,882	51,086	51,291	51,496	51,703
Wgtd Avg ADR Shrs (Dil) - '000s	8,910	29,866	29,866	60,000	22,192	60,000	43,014	80,120	80,441	80,763	81,087	81,412	81,738	82,065	82,394	82,724

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.

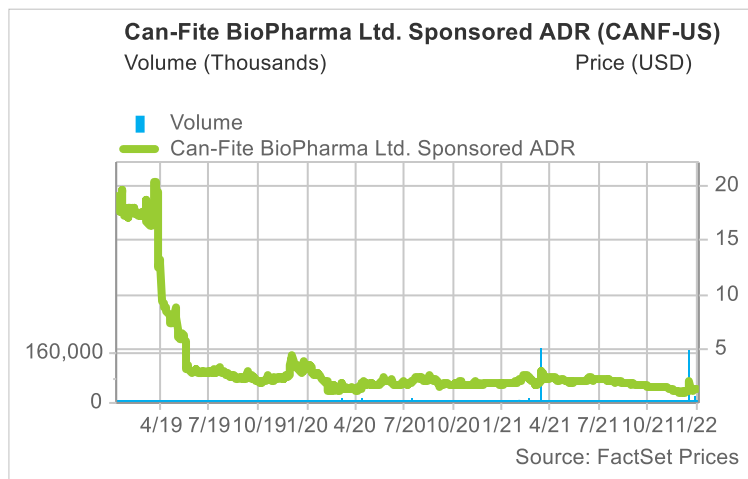
Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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

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- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 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.

Current as of... 20-Dec-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	68%	5	19%
Market Perform (Neutral)	12	32%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	38	100%	5	13%

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