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Can-Fite BioPharma Ltd. (NYSE/CANF)

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BUY: FDA – Green Light Piclidenoson in Kids

Can-Fite announced that it received a positive response from the FDA on the Pediatric Study Plan for the treatment of children suffering from psoriasis with Piclidenoson. The plan has been submitted to allow enrollment of children with psoriasis to Can-Fite's upcoming Phase 3 pivotal clinical psoriasis studies, aiming at registration of Piclidenoson with both the FDA and the European Medicines Agency (EMA) for the treatment of plaque psoriasis.

Investment Highlights:

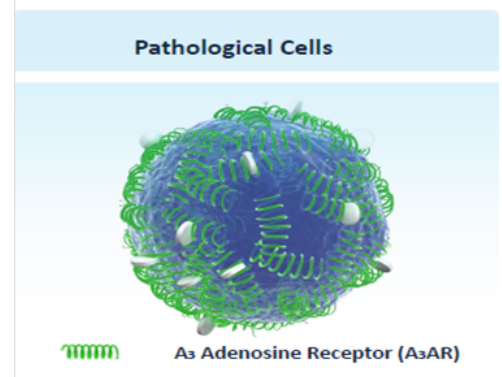
Piclidenoson: Preparatory Work for Pivotal Phase III Psoriasis Study; Can-Fite Received a "Green Light" from FDA and EMA— Following positive responses from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for its registration plan and pivotal Phase III study protocol for Piclidenoson in the treatment of moderate to severe psoriasis, the Company is preparing for study initiation. The FDA requested two Phase III studies and also encouraged the Company to enroll adolescent patients due to Piclidenoson's strong safety profile demonstrated over its development history and prior clinical studies.

About Kids: (press release): The plan has been submitted to allow enrollment of children with psoriasis to Can-Fite's upcoming Phase 3 pivotal clinical psoriasis studies, aiming at registration of Piclidenoson with both the FDA and the European Medicines Agency (EMA) for the treatment of plaque psoriasis. There is a high market need for a safe and efficacious drug for the treatment of children who suffer from psoriasis. There are a couple of small molecule or biological drugs on the market, however all have safety issues and are not satisfactory regarding efficacy. Therefore, there is a high market need which will enable Can-Fite to position Piclidenoson with its favorable safety and good efficacy as a treatment for this chronic and devastating disease. Can-Fite believes the inclusion of children in one or both of the Phase 3 studies significantly broadens any future market launch potential of the drug. Psoriasis affects millions of people worldwide, including a significant number of children who endure the physical and emotional burden of this challenging disease.

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 FCFF, 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 | \$2.03 |
| Price Target | \$6.00 |



Source: Can-Fite

| Stock Data | | | |
|---|-------------|---|--------|
| 52-Week Range | \$1.52 | - | \$7.20 |
| Shares Outstanding (mil.) | 1,359.8 | | |
| Market Capitalization (mil.) | \$2,753.7 | | |
| Enterprise Value (mil.) | \$1.1 | | |
| 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 | 1.6% | | |
| Short interest (mil.) | 0.0% | | |
| Dividend / Yield | \$0.00/0.0% | | |

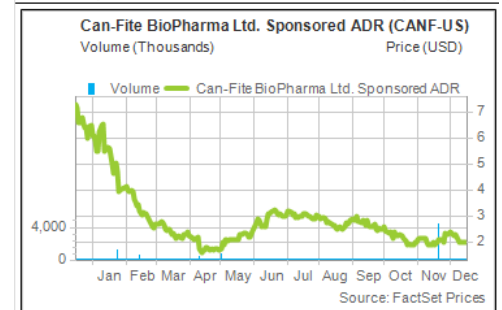


Exhibit 1. Income Statement

| Can-Fite Biopharma.: Income Statement (\$'000) | | | | | | | | | | | | | | | | |
|---|----------|----------|----------|----------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| .. YE December 31 | 2019A | 2020A | 2021A | 2022A | 1Q23A | 2Q23A | 3Q23A | 4Q23E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E |
| Revenue: | 2,032 | 763 | 853 | 810 | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Rheumatoid Arthritis U.S. | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Rheumatoid Arthritis EU | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Psoriasis U.S. | - | - | - | - | - | - | - | - | - | - | - | - | 53,044 | 110,375 | 172,251 | 238,947 |
| Piclidensoson (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 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Rheumatoid Arthritis U.S. | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Royalty Rate from Global Partnership | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Rheumatoid Arthritis EU | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Royalty Rate from Global Partnership | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Piclidensoson (CF-101), Psoriasis U.S. | - | - | - | - | - | - | - | - | - | - | - | - | 13,261 | 27,594 | 43,063 | 59,737 |
| Royalty Rate from Global Partnership | - | - | - | - | - | - | - | - | - | - | - | - | 26% | 26% | 26% | 26% |
| Piclidensoson (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 | 196 | - | 588 | - | 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 | 1,356 | 1,299 | 1,200 | 5,916 | 6,034 | 6,155 | 6,278 | 6,404 | 6,532 | 6,662 | 6,796 |
| General and Administrative | 3,059 | 2,951 | 3,845 | 3,143 | 847 | 624 | 762 | 750 | 2,983 | 3,132 | 3,289 | 3,453 | 3,626 | 3,807 | 3,998 | 4,197 |
| Total Expenses | 14,035 | 14,902 | 13,695 | 10,906 | 2,908 | 1,980 | 1,473 | 1,950 | 8,899 | 9,166 | 10,434 | 11,792 | 18,457 | 25,645 | 33,386 | 41,714 |
| Operating Income (Loss) | (12,003) | (14,139) | (12,842) | (10,096) | (2,712) | (1,784) | (1,277) | (1,950) | (7,723) | (9,166) | (5,483) | (1,009) | 24,892 | 52,885 | 83,096 | 115,659 |
| Finance expenses | 693 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Finance income | 3,109 | (304) | 227 | (77) | 162 | 114 | 103 | - | - | - | - | - | - | - | - | - |
| Total Other Income | 2,416 | (304) | 227 | (77) | 162 | 114 | 103 | - | - | - | - | - | - | - | - | - |
| Pretax Income | (9,587) | (13,835) | (12,615) | (10,173) | (2,550) | (1,670) | (1,174) | (1,950) | (7,723) | (9,166) | (5,483) | (1,009) | 24,892 | 52,885 | 83,096 | 115,659 |
| Taxes on income | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Taxes | - | (715) | (2,590) | - | - | - | - | - | - | (458) | (439) | - | 1,245 | 5,289 | 13,295 | 28,915 |
| 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) | (1,670) | (1,174) | (1,950) | (7,723) | (9,166) | (5,483) | (1,009) | 23,648 | 47,597 | 69,801 | 86,744 |
| GAAP-EPS | (1.77) | (1.02) | (0.58) | (0.28) | (0.31) | (0.20) | (0.09) | (0.16) | (0.75) | (0.54) | (0.30) | (0.05) | 1.27 | 2.55 | 3.72 | 4.60 |
| GAAP-EPS (Dil) | (1.35) | (0.48) | (0.33) | (0.13) | (0.43) | (0.28) | (0.09) | (0.16) | (0.84) | (0.51) | (0.27) | (0.05) | 1.17 | 2.34 | 3.42 | 4.23 |
| Wgtd Avg ADR Shrs (Bas) - '000s | 5,833 | 17,191 | 21,416 | 37,202 | 8,298 | 8,298 | 12,358 | 12,370 | 10,331 | 16,906 | 18,478 | 18,552 | 18,626 | 18,701 | 18,776 | 18,851 |
| Wgtd Avg ADR Shrs (Dil) - '000s | 8,910 | 29,866 | 38,014 | 80,120 | 6,000 | 6,000 | 12,358 | 12,370 | 9,182 | 18,111 | 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.

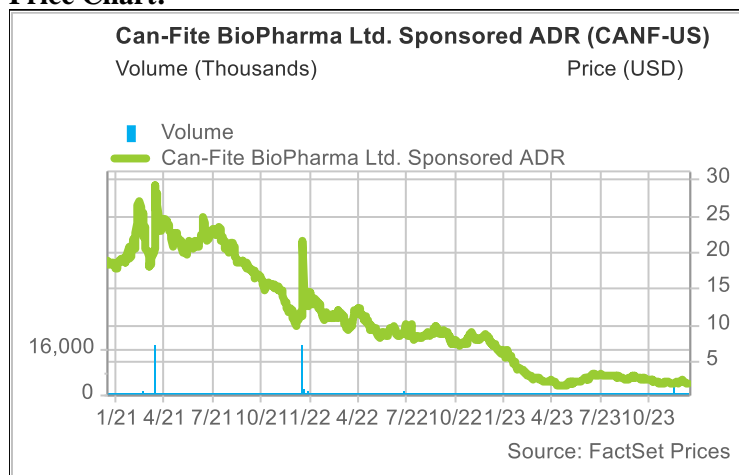
Partnership risk. Can-Fite may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the Company will be able to secure a favorable partnership.

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:

- 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
Update – Buy – July 18, 2023 – Price Target \$6.0
Update – Buy – August 31, 2023 – Price Target \$6.0
Update – Buy – November 30, 2023 – Price Target \$6.0
Update – Buy – December 4, 2023 – Price Target \$6.0
Update – Buy – December 13, 2023 – Price Target \$6.0
Update – Buy – December 18, 2023 – Price Target \$6.0

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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 14-Dec-23

| | Company Coverage | | Investment Banking | |
|-----------------------------|-------------------------|-------------|---------------------------|---------------|
| Ratings Distribution | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 21 | 61.76% | 4 | 11.80% |
| Market Perform (Neutral) | 13 | 38.24% | 2 | 5.90% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0.00% |
| Total | 34 | 100% | 6 | 17.70% |

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