CAN-FITE BioPharma Ltd

NYSE American: **CANF**

Market Data

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Industry	Biotech
Price	$1.97
52-Wk Range	$1.71-$3.33
Market Cap	$11.8M
ADS Out.	6.0M
Institutional Own.	4.9%
Avg. Vol. (90-day)	19,367
Revenue (ttm)	$0.7M
Cash (mrq)[1]	$8.9M
LT Debt (mrq)	$0M

Price data as of April 29, 2024

[1] includes cash and cash equivalents and short-term deposits

ANALYST COVERAGE:
HC Wainwright
Buy Rating / $18 price target

Alliance Global Partners
Buy Rating / $12 price target

Auditor:
Kost Forer Gabbay & Kasierer

Legal Counsel:
Greenberg Traurig

Transfer Agent:
BNY Mellon

canfite.com

Company Overview

Can-Fite BioPharma is an advanced clinical stage drug development company with a platform of oral drugs designed to address multi-billion-dollar markets in the treatment of oncology and inflammatory diseases. The Company has 2 drug candidates in advanced stages of development, Piclidenoson for the treatment of psoriasis and Namodenoson for the treatment of advanced liver cancer. For each of the drugs, a registration plan has been agreed with both the U.S. FDA and the European Medicines Agency (EMA) and enrollment of patients for a pivotal Phase III clinical study is ongoing for liver cancer and underway for psoriasis. Namodenoson also has a robust anti-cancer effect against pancreatic cancer and a Phase IIa clinical study will be initiated in Q2 2024. Due to the liver-protective effect of Namodenoson, a Phase IIb study for the treatment NASH (MASH), is currently enrolling patients. Piclidenoson and Namodenoson have an excellent safety profile with experience in over 1,600 patients in clinical studies to date.

Partnerships and Out-Licensing Deals

ewo pharma	Eastern Europe	*Psoriasis, Liver Cancer, MASH Pancreatic cancer*
Gebro Pharma	Spain, Switzerland, Austria	*Psoriasis*
CMS 康哲药业	China, Taiwan, Hong Kong, Macao	*Psoriasis, Liver Cancer, MASH*
Chong Kun Dang Pharm	South Korea	*Liver Cancer, MASH*
KYONGBO	South Korea	*Psoriasis*
cipher	Canada	*Psoriasis*
VETBIOLIX	Global	*Piclidenoson - Pets' Osteoarthritis*

$20M received in upfront and milestone payments

$130M potential based on regulatory and sales milestones

Typical Deal Structure

- Up-front money upon signing a distribution deal
- Regulatory milestone payments
- Royalties (double-digits)
- Sales milestone payments

Value Proposition

Can-Fite BioPharma is focused on developing small molecule drugs targeting the A3 adenosine receptor (A3AR), a unique approach in treating pathological conditions including cancer and inflammatory diseases. The Company's robust pipeline includes advanced-stage clinical candidates demonstrating promising efficacy and safety profiles for psoriasis and liver disease.

Strategically positioned with multiple out-licensing deals and potential milestone payments totaling over $130 million, Can-Fite has already received $20 million in upfront and milestone payments, underscoring the potential of its therapies. The Company has secured Fast Track and Orphan Drug designations from the FDA and EMA for its liver disease candidate, enhancing its regulatory pathway.

With advanced-stage assets targeting unmet medical needs in markets with a combined value in excess of $70 billion, Can-Fite is well positioned for the potential commercialization of its innovative therapies and has buy ratings from HC Wainwright and Alliance Global Partners with a median price target of $15 per share.

Development Pipeline

Piclidenoson

Pivotal Phase III Psoriasis Study

A registration plan with a pivotal Phase III study design was agreed upon with the FDA and EMA. The prior Phase III Comfort™ trial enrolled >400 patients with moderate-to-severe psoriasis. Patients treated with Piclidenoson had a statistically significant progressive improvement along the study period compared to placebo. Piclidenoson's excellent safety profile was comparable to that of placebo and better than Otezla, a leading oral psoriasis drug on the market.

Namodenoson

Pivotal Phase III in Advanced Liver Cancer – Enrollment Ongoing

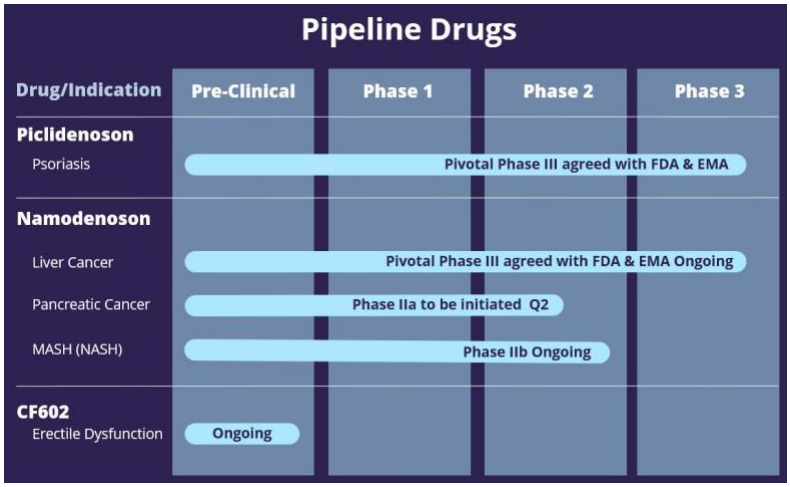
A registration plan with a pivotal Phase III study design was agreed upon with the FDA and EMA. Namodenoson has Orphan Drug status with both the FDA and EMA, as well as Fast Track Status with the FDA for the treatment of advanced liver cancer. Namodenoson is being evaluated as a 2nd or 3rd line treatment with the primary endpoint of improved overall survival. An interim analysis will be conducted after 50% of the planned 450 patients are enrolled and treated.

Exploratory Phase II in Pancreatic Cancer

An exploratory open-label Phase IIa study to assess the efficacy and safety of Namodenoson in the treatment of patients with pancreatic cancer who have received at least one previous systemic therapy is underway.

NASH (MASH) Phase IIb – Enrollment Ongoing

Namodenoson is in a Phase IIb NASH (MASH) multicenter, randomized, double-blind, placebo-controlled study with biopsy-confirmed NASH and F1-3 fibrosis. The former Phase IIa study met all efficacy and safety endpoints.



Investment Highlights

Advanced clinical pipeline

- Piclidenoson in late-stage trials for psoriasis, showing significant anti-psoriatic effects and a favorable safety profile
- Namodenoson has secured pivotal Phase III agreements with the FDA and EMA for treating liver cancer and demonstrated safety and efficacy in Phase II studies

Enhanced regulatory pathway and strong commercial potential

- Received Fast Track and Orphan Drug designations from the FDA and EMA for Namodenoson
- Established out-licensing agreements, with potential for $130 million in milestone payments; $20 million already received
- Diverse portfolio addresses large markets ($70B+) with significant unmet needs

Proven safety and efficacy

- Drugs have shown high efficacy and good safety in clinical trials involving over 1,600 patients

Buy ratings with $15 per share median price target from HC Wainwright and Alliance Global Partners