Zacks Small-Cap Research

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Can Fite Biopharma (CANF-NYSE)

CANF: Valuation Attractive

CANF: Phase III of CF101 for RA initiated; Phase II trial of CF102 for NASH also initiated. Fair Value stands at $9.50 using relative valuation methodology.

Current Price (11/28/17)	$1.47
Valuation	**$9.50**

OUTLOOK

Can-Fite's lead compounds, CF101 and CF102, are first-in-class agonists of the A_3AR receptor and have shown activity in a number of indications including rheumatoid arthritis (RA), psoriasis, and cancer. The company has initiated a Phase III trial with CF101 in RA and plans to initiate a Phase III in psoriasis in 2018. New positive data from Phase II/III of CF101 for psoriasis has increased the probability of success in advanced study. A Phase II trial of CF102 in patients with HCC is ongoing.

The expansion of CF102 into NASH convinces us that the company's share price has enough room for further appreciation.

SUMMARY DATA

52-Week High	**$2.46**
52-Week Low	**$1.37**
One-Year Return (%)	**-34.96**
Beta	**1.19**
Average Daily Volume (sh)	**27,252**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$24**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 A	0 E	0 E
2018					0 E
2019					25 E

Earnings Per ADR

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.13 A	-$0.08 A	-$0.28 A	-$0.01 A	-$0.50 A
2017	-$0.08 A	-$0.12 A	-$0.15 A	-$0.22 E	-$0.59 E
2018					-$0.95 E
2019					-$0.34 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Update on First Nine-Month 2017 Financials

Can-Fite reported revenue of $0.74 million for the nine months ended September 30, 2017, which compared to revenue of $0.18 million for the nine months ended September 30, 2016. The reason revenue increased in the first nine months of 2017 was that Can-Fite received the payment of $0.5 million in August 2017 from its partner Chong Kun Dang Pharmaceuticals (CKD).

R&D expenses for the first three quarters of 2017 were $3.6 million, compared to $4.38 million for the first three quarters of 2016. The company attributed the reduction in R&D expenses to a reduction in preclinical studies of CF602.

G&A expenses for the first three quarters of 2017 were $2.12 million, compared to a G&A expenses of $2.23 million for the first three quarters of 2016. The light decrease was mainly because of a decrease in investor relations expenses during the first nine months in 2017.

Net loss for the first three quarters ended September 30, 2017 was $3.90 million, compared to a net loss of $5.54 million for the prior period in 2016.

At September 30, 2017, the company had cash and cash equivalents of $5.11 million.

In August 2017, Can-Fite received a milestone payment of $0.5 million from its Korean partner Chong Kun Dang Pharmaceuticals (CKD), which licensed the exclusive right to distribute Namodenoson for the treatment of liver cancer in Korea upon regulatory approvals. The payment was part of a deal worth up to $3 million in upfront and milestone payments plus 23% royalties.

Current cash at hand can carry the company's operations into first half of 2018 according to our financial model.

Update on CF102 (Namodenoson) for NASH

On November 27, 2017, Can-Fite announced that the company has enrolled the first patient in the **Phase II** trial of Namodenoson (CF102) for the treatment of non-alcoholic fatty liver disease **(NAFLD)** and non-alcoholic steatohepatitis **(NASH)** in Israel.

Can-Fite estimates the cost of this Phase II trial to be less than $1 million.

The Phase II trial is a multicenter, randomized, double-blinded, placebo-controlled, dose-finding study of the efficacy and safety of Namodenoson in the treatment of NAFLD/NASH. Approximately **60 patients** with NAFLD, with or without NASH, will be enrolled in **three arms**, including two different dosages of Namodenoson and a placebo, given via oral tablets twice daily.

- The **primary endpoints** will be percent change from baseline in liver triglyceride (fat) concentration measured by nuclear magnetic resonance spectroscopy (NMRS) and safety.
- **Secondary endpoints** are the effects of Namodenoson on metabolic abnormalities in subjects with NAFLD, including body weight, waist circumference, serum triglyceride and high-density lipoprotein cholesterol levels, and serum liver transaminase.
- In addition, an assessment of the pharmacokinetics (PK) of Namodenoson and the A3 adenosine receptor (A3AR) biomarker will be evaluated prior to treatment and its correlation to patients' response to the drug will be analyzed upon study conclusion.

- Furthermore, the **exploratory objective** of this study is to evaluate the effects of Namodenoson on relevant biomarkers, such as adiponectin, leptin, C-reactive protein (CRP), and liver stiffness as determined by Fibroscan.

The Implications

We believe the expansion of CF102 into NASH represents an important milestone for Can-Fite in its clinical development.

Non-alcoholic fatty liver disease (NAFLD) is the build-up of extra fat in liver cells that is not caused by alcohol. It is normal for the liver to contain some fat. However, if more than 5% - 10% percent of the liver's weight is fat, then it is called a fatty liver (steatosis). The more severe form of NAFLD is called non-alcoholic steatohepatitis (NASH). NASH causes the liver to swell and become damaged.

NAFLD affects about 30% of adults and 10% of children in the US, among which 10-30% will develop NASH. 25-40% NASH patients will develop progressive liver fibrosis, while 20-30% NASH patients with advanced fibrosis will develop cirrhosis, which could lead to liver cancer.

NAFLD/NASH represents a multibillion-dollar market, but currently there are no FDA approved medicines for the treatment of NAFLD/NASH.

CF102 is currently being evaluated as a second-line treatment for HCC through a global **Phase II** trial. The addition of NASH further expands CF102's **liver disease franchise**.

CF102 has been granted **orphan drug status** and **fast track designation** for liver cancer by the US FDA. In October 2015, the European Medicines Agency (EMA) granted Orphan Drug Designation to CF102 for the indication of HCC.

The Ongoing Phase II Trial of CF102 for Liver Cancer

Can-Fite initiated a **global Phase II** trial in December 2014. This is a randomized, double-blind, placebo controlled trial to be conducted in the **U.S., Europe and Israel** with an estimated **78 patients** to be enrolled. CF 102 is being evaluated for efficacy and safety as a **second-line** treatment for advanced HCC in subjects with **Child-Pugh B** cirrhosis who failed Nexavar (sorafenib) as a first line treatment. Patients are treated twice daily with 25 mg of CF102.

The **primary endpoint** of the study is overall survival. **Secondary endpoints** include: time to progression (TTP), progression-free survival (PFS), objective response (OR) rate, disease control (DC) rate, safety, and the relationship between outcomes and A3AR expression.

In early August 2017, Can-Fite announced that the Phase II liver cancer clinical trial for **Namodenoson (CF102**) has successfully enrolled and randomized all **78 patients**.

As is standard in this indication, the primary endpoint of OS requires following the entire patient population until the statistically predetermined number of events occur. Can-Fite is following the survival data closely and will perform the survival analysis at the earliest possible opportunity.

CF102 has Orphan Drug Status in the U.S. and in Europe for the treatment of HCC. CF102 is approved for Compassionate Use for liver cancer by Israel's Ministry of Health.

Update on CF101 (Piclidenoson) Phase III Study for RA

In August 2017, Can-Fite successfully concluded a cardiodynamic trial for its lead drug candidate Piclidenoson, which showed favorable safety data required by the FDA and the European Medicines Agency (EMA) prior to initiation of Phase III studies.

In **late October** 2017, Can-Fite enrolled and dosed the first patient in its **Phase III ACRobat** trial of Piclidenoson (CF101) for first line treatment of rheumatoid arthritis (RA).and for the replacement for Methotrexate (MTX) in RA. MTX is the current standard of care for rheumatoid arthritis.

ACRobat is a global **Phase III** trial that will enroll approximately **500 patients** in Europe, Canada and Israel. The estimated cost of the entire Phase III study is approximately $5 million.

The EMA suggested Piclidenoson should be developed as an **alternative to MTX**, the most widely prescribed rheumatoid arthritis drug in the world. The EMA further suggested that this pivotal Phase III study will serve as the **first of two pivotal studies** required for drug approval.

The Phase III trial will be a randomized, double-blind, active and placebo-controlled trial to establish non-inferiority of Piclidenoson versus MTX, conducted in approximately **500 patients worldwide**.

- Piclidenoson at 1 mg and 2 mg or placebo will be administered twice daily, and MTX or placebo will be administered once weekly.
- **The primary endpoint** will be Low Disease Activity as measured by Disease Activity Scores at week 12.
- The trial will also evaluate **key secondary endpoints**, including American College of Rheumatology (ACR) score 20, 50 and 70 and the correlation between A3AR expression at baseline and patients' response to Piclidenoson. Based on Can-Fite's Phase II clinical studies with CF101 in patients with active rheumatoid arthritis, the percentage of patients with high expression of A3AR is estimated to be approximately 70%.
- To establish longer-term clinical efficacy and safety, the trial will continue for a period of 24 weeks.

Over the several clinical experiences with CF101 for RA, Can-Fite has learned and identified the relationship between A_3AR expression and response for CF101. Based on these findings, the company's last Phase IIb trial demonstrated positive data of CF101 for the treatment of RA patients based on the level of A_3AR expression. The planned Phase III trial uses the same criteria for screening RA patients, and therefore has a high possibility that it will replicate the results of the last Phase IIb trial.

Although approximately 90% of rheumatoid arthritis patients receive MTX at some point in their disease according to the Arthritis Foundation of America, 40-50% of patients stop taking MTX after five years, primarily due to the presence of serious side-effects, as indicated in some published studies. Other studies show that between 10% and 30% of patients are intolerant of MTX, creating a significant need in the market for a new, safe and effective treatment option.

We believe Piclidenoson can offer a superior alternative to MTX.

Update on CF101 for Psoriasis

Phase III Trial Will Start in 2018

In early June 2016, Can-Fite submitted its protocol design to the European Medicines Agency **(EMA)** for a **Phase III** trial and registration plan for **Piclidenoson (CF101)** in the treatment of **psoriasis**. This followed a pre-submission meeting the Company had with the EMA.

In Nov 2016, the company reached an agreement with the EMA on the final design of a global pivotal Phase III trial for Piclidenoson (CF101) in the treatment of psoriasis.

The planned Phase III trial is a randomized, double-blind, placebo- and active-controlled study that will investigate the efficacy and safety of daily Piclidenoson administered orally as compared to placebo as its **primary endpoint** and as compared to apremilast (Otezla®) as its **secondary endpoint** in approximately **400 patients** with moderate-to-severe plaque psoriasis. Medication is to be taken orally twice daily for 32 weeks in a double-blinded fashion.

The primary end point will be the proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response of ≥75% (PASI 75) vs. placebo at week 16. The secondary endpoints will include non-inferiority to **Otezla®** on week 32 and efficacy and safety data for CF101 through the extension period of up to 48 weeks of treatment. Patients will be selected to the study based on over expression of the A3AR biomarker.

The rationale of comparing Piclidenoson to Otezla®, the recently registered oral drug marketed by Celgene, is based on data from Can-Fite's prior Phase II/III study that showed at weeks 24 and 32, Piclidenoson's efficacy as measured by PASI compares well to Otezla® in its Phase III trial.

Can-Fite intends to initiate the Phase III trial in **2018**.

Attractive Valuation

We maintain our fair value for CANF at $9.50 per share based on the recent achievements the company has made.

Can-Fite is a **late stage** development biopharmaceutical company focused on the development of orally available small molecule therapeutic products for the treatment of autoimmune-inflammatory, oncological, and sexual dysfunction. The company has three lead candidates in each category: **CF101** for autoimmune disease (RA and Psoriasis), **CF102** for liver cancer/NASH, and **CF602** for sexual dysfunction.

The most advanced candidate is CF101. Can-Fite has completed a couple of Phase II studies of CF101 for **RA** with the most recent one achieving statistically significance based on the A_3AR expression level as enrollment criteria. The company has initiated the **Phase III ACRobat** trial of CF101 for RA using the same enrollment criteria.

For **psoriasis**, Can-Fite also completed a Phase II and a Phase II/III study of CF101. The Phase II study achieved statistically significant results, but the Phase II/III failed its initial primary endpoint (PASI75 in 12 weeks). However, further analysis indicated that CF101 achieved multiple statistically significant results (PASI50, 75, 90, 100 in 32 weeks). We think the cumulative and linear improvement in CF101's efficacy over a longer period of time is a very significant finding for the psoriasis treatment market. Based on the new data and the favorable safe profile, Can-Fite has submitted its protocol design to the European Medicines Agency **(EMA)** for a **Phase III** trial and registration plan for **Piclidenoson (CF101)** in the treatment of **psoriasis** and the company plans to initiate the trial in **2018**.

We are especially encouraged by the fact that CF101 has the potential as a **first-line systemic therapy** for patients with moderate-severe psoriasis and for patients who do not want to be treated with the current systemic drugs due to safety issues. Currently there is no universally accepted first-line systemic therapy for patients diagnosed with psoriasis, and therefore CF101, an orally bioavailable drug with an excellent safety profile can be positioned for this unmet need.

We would like to mention the company’s Phase II/III trial of CF101 for psoriasis. Initial results failed the primary endpoint (PASI75 in 12 weeks). However, further analysis of the data indicated that CF101 achieved multiple positive results including PASI50, 75, 90, and 100 in 32 weeks. Moreover, the PASI 90 subset analysis further suggests a higher and significant (p=0.026) CF101 response rate of 26.9% among patients previously **untreated** with systemic psoriasis therapy compared to patients pre-treated with systemic drugs. Based on the new data, we believe CF101 has the increased probability to succeed in the newly planned advanced Phase III trial.

For **CF102**, Can-Fite is conducting a **global Phase II** trial as a second line treatment for advanced HCC in subjects with **Child-Pugh B** cirrhosis who failed Nexavar (sorafenib) as a first line treatment. Top line data from this Phase II trial are expected to be available soon. Can-Fite’s strategy to test CF102 in HCC

patients who are Child-Pugh B and have failed sorafenib is very risky, however it is warranted based on the positive preclinical data and Phase I/II data showing the drug to be both safe and effective in that cohort. The reward could be immense if the strategy pays off, as there is no current treatment option for advanced liver cancer patients. Can-Fite also expanded CF102 into NASH and a Phase II clinical trial has been initiated.

We believe the expansion of CF102 into NASH represents an important milestone for Can-Fite in its clinical development.

Based on the company's fundamentals, we think current market price does not reflect the intrinsic value of Can-Fite anymore.

For RA, the company has initiated the Phase III trial. We expect the company to file an NDA in 2018. If everything goes Can-Fite's way, CF101 will receive approval in late 2018 or early 2019. For psoriasis, the company will initiate the Phase III trial in 2018, file an NDA in late 2018, and get approval in 2019.

Based on our long term financial model, Can-Fite will achieve profitability in 2020 with an earnings of $0.78 per ADS based on total revenue of $85 million. We believe a P/E multiple of 28 x is appropriate for the valuation of the company. Based on this relative valuation metric, we come up with a price target of $9.50 per ADS using 30% discount rate for 3 years. Our price target values the company at $162 million based on 17 million ADS outstanding. This is still conservative in our view.

But keep in mind **the risks**. Our valuation assumes the final approval of the company's clinical programs including RA, psoriasis and liver cancer. Any clinical/regulatory failure or delay will have a significant negative impact on the company's shares. Cash burn is also on our close watch list. As the company moves its clinical programs into advanced stage, R&D expenses will soar. Current cash balance can only last into 2017. The company will need to tap the capital market for further financing before it become cash flow positive in 2020. Any equity related financing will dilute existing shareholder base and will have negative impact on share price. But overall, the company has a favorable risk/award profile for investors with a long-term investment horizon.

PROJECTED INCOME STATEMENT

Can-Fite Biopharma Ltd.	Q1	Q2	Q3	Q4	2016 A	Q1	Q2	Q3	Q4	2017 E	2018 E	2019 E	2020 E
CF101 (Psoriasis)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$10	$35
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*250%*
CF101 (RA)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$15	$45
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*200%*
CF101 (Glaucoma)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
CF102 (HCC)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	($0)	$0	$0	$0	$1	$0	$1	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**($0)**	**$0**	**$0**	**$0**	**$1**	**$0**	**$1**	**$0**	**$25**	**$85**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*240%*
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5	$17
Product Gross Margin	-	-	-	-	-	-	-	-	-	-	-	*80%*	*80%*
Research & Development	$1.1	$1.5	$1.5	$2.0	$6.1	$1.2	$1.3	$1.1	$2.8	$6.4	$10.0	$12.0	$16.0
General & Administrative	$0.6	$0.7	$0.8	$0.6	$2.7	$0.8	$0.7	$0.7	$1.2	$3.3	$8.0	$15.0	$25.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($1.7)	($2.1)	($2.3)	($2.6)	($8.6)	($1.9)	($1.9)	($1.1)	($4.0)	($9.0)	($18.0)	($7.0)	$27.0
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*32%*
other net	($0.1)	$0.9	($1.7)	$2.5	$1.6	$0.7	($0.2)	($1.6)	$0.0	($1.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($1.8)	($1.2)	($3.9)	($0.1)	($7.0)	($1.3)	($2.2)	($2.7)	($4.0)	($10.1)	($18.1)	($7.1)	$26.9
Income Taxes Paid	($0.0)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$9.5
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*35%*
Net Income	**($1.8)**	**($1.2)**	**($3.9)**	**($0.1)**	**($7.0)**	**($1.3)**	**($2.2)**	**($2.7)**	**($4.0)**	**($10.1)**	**($18.1)**	**($7.1)**	**$17.4**
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	*21%*
Reported EP ADR	**($0.13)**	**($0.08)**	**($0.28)**	**($0.01)**	**($0.50)**	**($0.08)**	**($0.12)**	**($0.15)**	**($0.22)**	**($0.59)**	**($0.95)**	**($0.34)**	**$0.78**
YOY Growth					-	-	-	-	-	-	-	-	-
Basic ADR Outstanding	14.00	14.00	14.00	14.08	14.02	15.50	17.50	17.50	18.00	17.13	19.00	21.00	22.50

Source: Company filings and Zacks estimates

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