Zacks Small-Cap Research

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Can Fite Biopharma (CANF-NYSE)

CANF: Zacks Company Report

CANF: Phase III of CF101 for RA to begin in 2Q17; Balance sheet boosted by new financing; Expanding CF102 into NASH

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 is set to initiate a Phase III trial with CF101 in RA soon and a Phase III in psoriasis in 4Q17. 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.

Current Price (04/20/17)	$1.85
Valuation	**$9.50**

SUMMARY DATA

52-Week High	**$3.09**
52-Week Low	**$1.79**
One-Year Return (%)	**-36.30**
Beta	**1.24**
Average Daily Volume (sh)	**23,688**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$31**
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)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 A	0 A	0 A
2017					0 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.22 A	-$0.21 A	-$0.12 A	-$0.20 A	-$0.75 A
2015	-$0.03 A	-$0.15 A	-$0.30 A	$0.01 A	-$0.45 A
2016	-$0.13 A	-$0.08 A	-$0.28 A	-$0.01 A	-$0.50 A
2017					-$0.75 E

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

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WHAT'S NEW

Can-Fite Exited Fiscal 2016 with a Strong Balance Sheet

For the fiscal year ended December 31, 2016, revenues were $0.17 million, compared to revenues of $0.17 million during the year ended December 31, 2015.

The revenues during 2016 were mainly due to the recognition of a portion of the CAD 1.65 million advance payment received in March 2015 under the distribution agreement with Cipher and a small amount due to the recognition of a portion of the U.S. $0.5 million advance payment received in December 2016 under the distribution agreement with CKD.

R&D expenses for the twelve months ended December 31, 2016 were $6.08 million, compared with $3.91 million for the same period in 2015. R&D expenses for the year ended 2016 comprised primarily of expenses associated with the Phase II study for Namodenoson as well as expenses for ongoing studies of Piclidenoson. The increase was primarily due to costs associated with preparations of the Piclidenoson Phase III studies in the treatment of rheumatoid arthritis and psoriasis and costs associated with the ongoing clinical trial of Namodenoson for treatment of liver cancer.

G&A expenses for fiscal 2016 were $2.73 million, compared to $2.76 million for the same period in 2015. The minor decrease was primarily due to a decrease in professional services.

Net loss for 2016 was $7.02 million, compared with a net loss of $5.14 million for the same period in 2015. The increase was primarily attributable to an increase in R&D expenses.

As of December 31, 2016, Can-Fite had cash and cash equivalents of $8.12 million. In addition, in January of 2017, Can-Fite raised U.S. $5 million in a registered direct offering.

In connection with the offering, the Company issued 2,500,000 registered American Depository Shares (ADSs) of Can-Fite at a purchase price of $2.00 per ADS. Additionally, for each ADS purchased by investors, the investors received an unregistered warrant to purchase 50% of an ADS. The warrants have an exercise price of $2.25 per ADS, shall be exercisable six months following the issuance date and will expire five and one-half years from the issuance date.

Also in December, 2016, Can-Fite received its first payment of $500,000 from Chong Kun Dang Pharmaceuticals (CKD). Can-Fite recently announced entering a distribution agreement with CKD for the exclusive right to distribute Namodenoson (CF102) for the treatment of liver cancer in South Korea, upon receipt of regulatory approvals, for up to $3 million in upfront and milestone payments, plus royalties on net sales of 23%.

The new financing not only boosts Can-Fite's balance sheet, but further validates its technology and clinical programs.

Current cash at hand can carry the company's operations into late 2017 according to our financial model.

Update on CF101 (Piclidenoson) Phase III Study for RA

On Feb. 8, 2017, Can-Fite announced through a news release that the Company is ready to commence patient enrollment **in the 2Q17** in its global **Phase III** trial of its lead drug candidate **Piclidenoson (CF101)** as a first line treatment for rheumatoid arthritis **(RA).** The trial, titled **ACRobat**, will enroll approximately **500 patients** in Europe, Canada and Israel.

The estimated cost of the entire Phase III study is approximately $5 million. This includes the cost of the global clinical research organizations that have been engaged to help conduct ACRobat. The required supply of Piclidenoson has already been manufactured and paid.

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 planned 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.

The company will file similar submissions in the U.S.

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 4Q2017

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 **4Q2017**.

New Data Presented Showing Piclidenoson May Offer Efficacy Similar to Industry Leading Biologics Without Harmful Side Effects

On July 7, 2016, Can-Fite presented **new findings** of **Piclidenoson (CF101)** at Psoriasis 2016, the 5th Congress of the Psoriasis International Network, in Paris, France.

New mechanism of action data indicated that **Piclidenoson** inhibits two inflammatory cytokines, interleukin 17 (IL-17) and interleukin 23 (IL-23) which are known to play a major role in the inflammatory process of psoriasis.

Biologic drugs for the treatment of psoriasis currently on the market and in development also work via a similar mechanism of action by inhibiting IL-17 and IL-23. These systemic drugs offer good efficacy, however, as biologics they can cause serious side effects.

Piclidenoson binds to the Gi protein associated A3 adenosine receptor (A3AR), which is over- expressed in psoriasis patients. This binding action has shown to induce a robust anti-inflammatory effect by inhibiting IL-17 and IL-23 as demonstrated in in-vitro studies. An orally administered small molecule drug, Piclidenoson, potentially offers safety superior to biologics as shown in clinical studies in approximately 1,000 people.

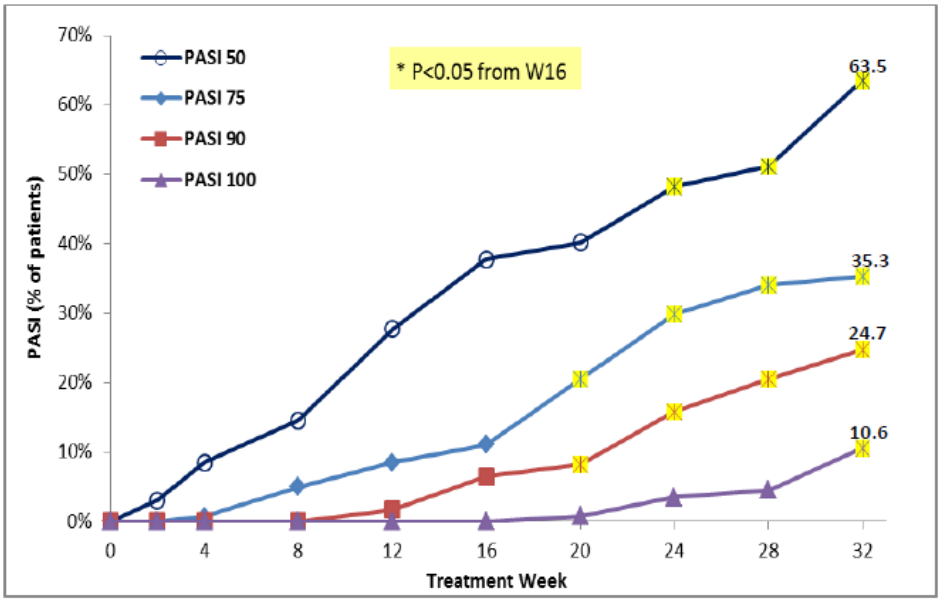
The **discovery** of this new mechanistic pathway of Piclidenoson will position it as a strong drug candidate to treat psoriasis with potential efficacy similar to biologics on the market today, while potentially offering superior safety as a small molecule oral drug.

Phase II/III Data Published in Peer Reviewed Journal

Data from the company’s completed Phase II/III multicenter, randomized, controlled trial of Piclidenoson (CF101) in the treatment of moderate to severe psoriasis. was published in the August 2016 issue of Journal of Drugs in Dermatology.

The published study provides details regarding patient population, safety profile, and Piclidenoson's efficacy as compared to **apremilast**, a drug approved by the FDA to treat moderate to severe psoriasis and is marketed under the brand name Otezla® by Celgene.

While the Phase II/III study did not meet its primary efficacy endpoint at week 12, Piclidenoson did show a statistically significant improvement on **week 32** in the PASI scores (50/75/90/100), a measure of efficacy in the treatment of psoriasis. Moreover, while biological drugs have been widely used in the past two decades for the treatment of moderate to severe psoriasis, these drugs can cease to be effective over time, with 67% of discontinuations attributed to loss of efficacy, based on a recent study.



Importantly, data from the published study suggest Piclidenoson's efficacy continues to improve over time. The recently approved small molecule drug **Otezla**, appears to plateau in efficacy beyond week 16 based on data from a Phase III trial of Otezla, while the Phase II/III study of Piclidenoson shows it continues to improve in efficacy through week 32 and compares favorably to Otezla as early as week 24.

Update on CF101 Phase II Glaucoma Study

On July 5, 2016, announced that its subsidiary, OphthaliX (OTC: OPLI) released top-line results from its **Phase II** clinical trial of CF101 for the treatment of **glaucoma**.

The **Phase II** trial is being conducted in **Europe and Israel** and full enrollment of **89 patients** has been achieved. The study is a randomized, double-masked, placebo-controlled, parallel-group study of the safety and efficacy of daily CF101 administered orally in subjects with elevated intraocular pressure (IOP). The objective of this study is to determine the safety and efficacy of oral CF101 in lowering IOP when administered twice a day for 16 weeks in subjects with elevated IOP.

The study is being conducted **with two cohorts** (44 patients in each cohort, 3:1 ratio). In the first cohort patients were treated with 1 mg CF101 and placebo. Blinded results from this cohort showed that the drug had a favorable safety profile and was well tolerated. In the second cohort, dosage was increased, with patients receiving 2 mg of CF101 and matching placebo, given orally every 12 hours for 16 weeks.

In this trial, no statistically significant differences were found between the CF101 treated group and the placebo group in the primary endpoint of lowering intra ocular pressure (IOP). CF101 was found to have a favorable safety profile and was well tolerated.

The company probably will discontinue the development of CF101 for glaucoma.

Update on CF102 for NASH

In early January 2017, Can-Fite received approval to commence patient enrollment in a **Phase II study** of **Namodenoson (CF102)** in the treatment of non-alcoholic fatty liver disease **(NAFLD),** the precursor to non-alcoholic steatohepatitis (NASH). Approval came from the Institutional Review Boards (IRBs) of Hadassah Medical Center and Rabin Medical Center, two leading medical institutions **in Israel** where the study will be conducted.

Can-Fite is ready to commence patient enrollment in the **2Q17.**

- The approved clinical protocol is a Phase II 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 expansion to the **Phase II** is based on the compelling **pre-clinical** data on CF102 in the treatment of NASH. The company recently concluded preclinical study of CF102 in liver disease. In the study, CF102 revealed its capability to improve liver pathology in a NAFLD (non-alcoholic fatty liver disease)/diabetes animal model of NASH.

Key points from the preclinical data of CF102:

- CF102 had a statistically significant reduction in NAFLD activity score compared to placebo.
- CF102 reduced liver-to-body weight compared to placebo.
- Representative photomicrographs of H&E-stained liver sections showed improved pathology in animals receiving CF102 vs. placebo.
- CF102 decreased plasma ALT and triglycerides levels in the livers of NASH-model compared to placebo.
- Liver sections from the placebo group exhibited severe micro- and macrovesicular fat deposits, hepatocellular ballooning and inflammatory cell infiltration, whereas the CF102 treated group showed a significant decrease in steatosis, ballooning and lobular inflammation compared to the placebo group.

In prior preclinical studies, CF102 has shown efficacy in the treatment of liver regeneration and function following liver surgery.

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, and disease control (DC) rate.

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.

Enrollment is ongoing and Can-Fite anticipates completing the enrollment **in 2Q17**.

Update on CF602

CF602 is an allosteric modulator that enhances the affinity of the natural ligand, adenosine, to the A3AR. In October 2015, Can-Fite reported new findings for its CF602 drug candidate showing a defined mechanism of action in **erectile dysfunction (ED)** similar to sildenafil (Viagra®) in a rat model of diabetes mellitus. CF602 demonstrated effects on erection superior to that of Viagra in animal studies.

In April 2016 Can-Fite reported new preclinical data for CF602, showing a statistically significant full recovery from erectile dysfunction after one single dose treatment in a **pre-clinical diabetic model**.

A Notice of Allowance was granted to Can-Fite by the U.S. Patent and Trademark Office in November, 2016 for the Company's patent application covering A3 adenosine receptor (A3AR) ligands for use in the treatment of erectile dysfunction. The patent addresses methods for treating erectile dysfunction with different A3AR ligands including CF602. With this new broader patent protection, Can-Fite has made a strategic decision to investigate additional compounds, owned by the Company, for the most effective and safest profile in this indication. As such, the Company will postpone its planned Investigational New Drug (IND) submission for this indication.

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 plans to initiate a **Phase III** trial of CF101 for RA in **2Q17** 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 **4Q2017**.

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 in **late 2017**. 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 is expected to be initiated in **2Q2017**.

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 will initiate the Phase III trial in 2Q2017, file an NDA in early 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 4Q2017, file an NDA in 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.

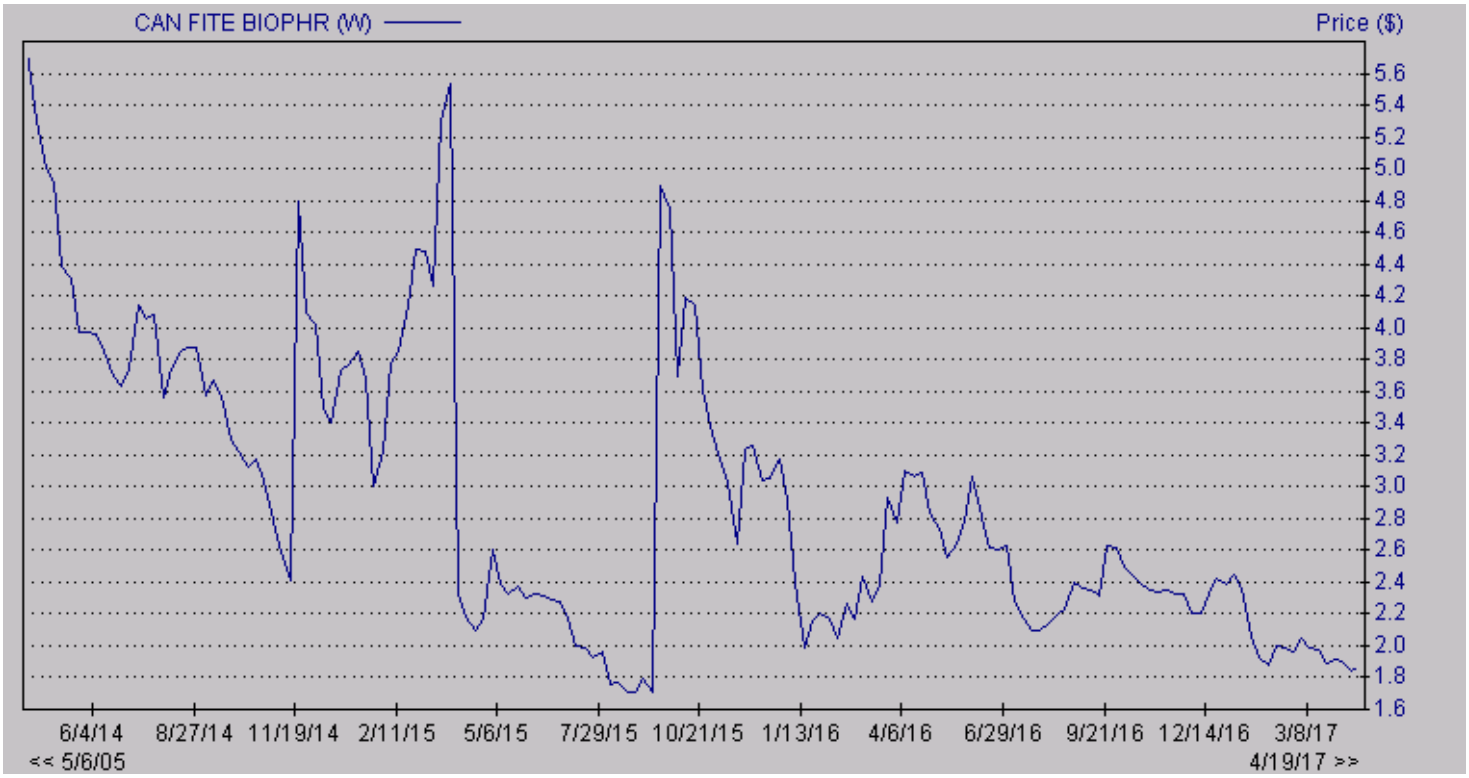
PROJECTED INCOME STATEMENT

Can-Fite Biopharma Ltd.	Q1 A	Q2 A	Q3 A	Q4 A	2015 A	Q1	Q2	Q3	Q4	2016 A	2017 E	2018 E	2019 E	2020 E
CF101 (Psoriasis)	$0	$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	$0	$15	$45
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*200%*
CF101 (Glaucoma)	$0	$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	$0	$5
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0	($0)	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**($0)**	**$0**	**$0**	**$0**	**$25**	**$85**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*240%*
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5	$17
Product Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	*80%*	*80%*
Research & Development	$0.6	$0.9	$0.9	$1.4	$3.9	$1.1	$1.5	$1.5	$2.0	$6.1	$8.0	$10.0	$12.0	$16.0
General & Administrative	$0.6	$0.6	$0.5	$1.0	$2.7	$0.6	$0.7	$0.8	$0.6	$2.7	$5.0	$8.5	$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	$0.0
Operating Income	($1.2)	($1.5)	($1.4)	($2.4)	($6.5)	($1.7)	($2.1)	($2.3)	($2.6)	($8.6)	($13.0)	($18.5)	($7.0)	$27.0
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	*32%*
Non-Operating Expenses (Net)	$0.8	($0.2)	($1.8)	$2.5	$1.4	($0.1)	$0.9	($1.7)	$2.5	$1.6	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($0.4)	($1.7)	($3.2)	$0.1	($5.2)	($1.8)	($1.2)	($3.9)	($0.1)	($7.0)	($13.1)	($18.6)	($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	$0.0	$9.5
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*35%*
Net Income	**($0.4)**	**($1.7)**	**($3.2)**	**$0.1**	**($5.2)**	**($1.8)**	**($1.2)**	**($3.9)**	**($0.1)**	**($7.0)**	**($13.1)**	**($18.6)**	**($7.1)**	**$17.4**
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	*21%*
Reported EP ADR	**($0.03)**	**($0.15)**	**($0.30)**	**$0.01**	**($0.45)**	**($0.13)**	**($0.08)**	**($0.28)**	**($0.01)**	**($0.50)**	**($0.75)**	**($0.98)**	**($0.34)**	**$0.78**
YOY Growth	-	-	-	-	-					-	-	-	-	-
Basic ADR Outstanding	10.93	11.64	10.73	12.61	11.48	14.00	14.00	14.00	14.08	14.02	17.50	19.00	21.00	22.50

Source: Company filings and Zacks estimates

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HISTORICAL STOCK PRICE



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