
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the Month of September 2015

001-36203
(Commission File Number)

CAN-FITE BIOPHARMA LTD.

(Exact name of Registrant as specified in its charter)

10 Bareket Street
Kiryat Matalon, P.O. Box 7537
Petach-Tikva 4951778, Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover
Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by
Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by
Regulation S-T Rule 101(b)(7): ____

This Report on Form 6-K (including exhibits thereto) is hereby incorporated by reference into the registrant's Registration Statements on Form F-3 (File Nos. 333-195124, 333-199033 and 333-204795), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

On September 9, 2015, Can-Fite BioPharma Ltd. (the “Company”) made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.1 and may be viewed in the Investor Information section of the Company’s website at www.canfite.com.

Exhibit Index

Exhibit No.	Description
99.1	Investor Presentation – September 2015

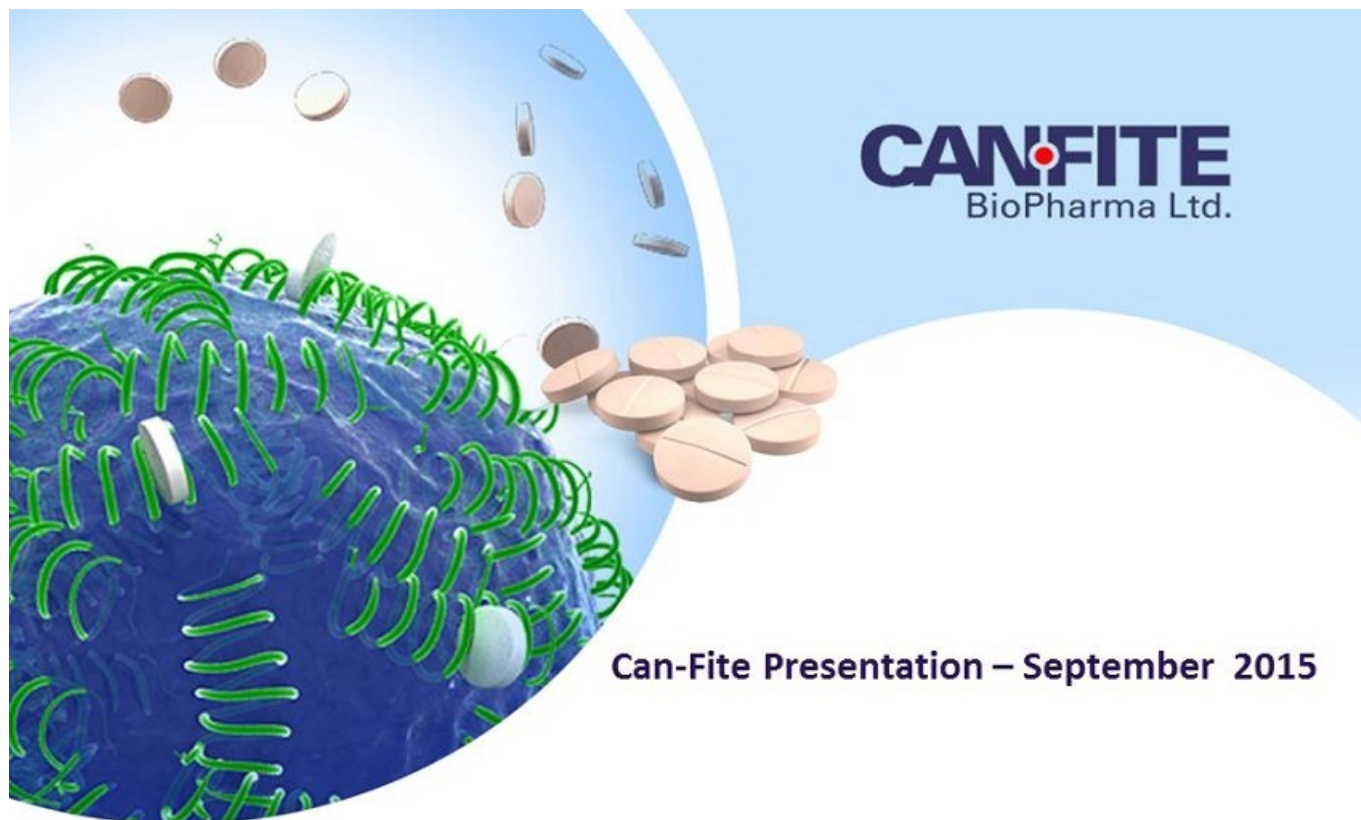
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Can-Fite BioPharma Ltd.

Date September 9, 2015

By: /s/ Pnina Fishman
Pnina Fishman
Chief Executive Officer



Small Molecules For Big Clinical Needs™

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(NYSE MKT:CANF) (TASE:CFBI)



Forward Looking Statement

This presentation contains forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, Can-Fite or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by Can-Fite with the U.S. Securities and Exchange Commission (the "SEC"), press releases or oral statements made by or with the approval of one of Can-Fite's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause Can-Fite's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause Can-Fite's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in Can-Fite's filings with the SEC and in its periodic filings with the Tel-Aviv Stock Exchange.

(NYSE MKT:CANF) (TASE:CFBI)

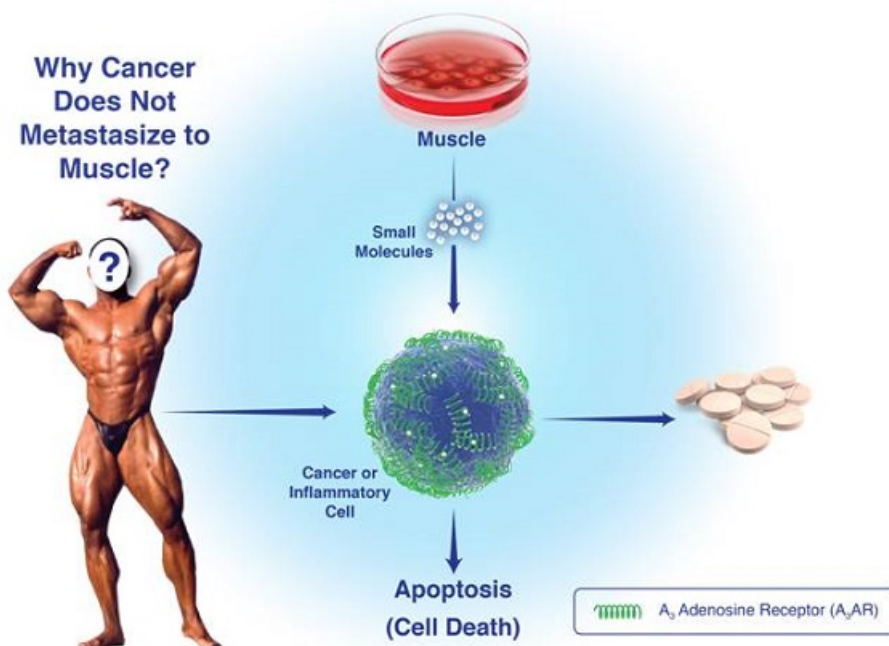


Company Profile

- **Advanced clinical stage drug development company**
 - Phase II and Phase II/III clinical studies
- **Small molecule drugs**
 - Autoimmune Inflammatory diseases
 - Cancer
 - Sexual Dysfunction
- **Company Operations**
 - Headquarters and Discovery Labs – Petach-Tikva, Israel
 - Drug Development & Clinical Operations – Boston, USA
- **Regional out-licensing deals; ~ \$10M received**
 - Canada: for rheumatoid arthritis and psoriasis
 - Korea: for rheumatoid arthritis

(NYSE MKT:CANF) (TASE:CFBI)

From Concept to Technology



(NYSE MKT:CANF) (TASE:CFBI)

Platform Technology

- **Therapeutic Target**

- A₃ adenosine receptor (A₃AR)
- Highly expressed in inflammatory and cancer cells

- **Drug product**

- Small molecules
- Orally bioavailable drugs

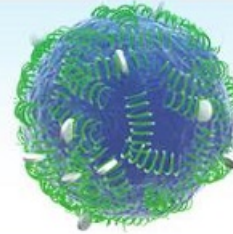
- **Therapeutic Effect**

- Anti-inflammatory and anti-cancer effects in Phase II studies; Excellent safety profile

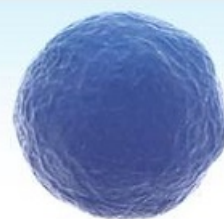
- **A₃AR is utilized as Predictive Biomarker**

- Used to predict patient's response to the drug

Inflammatory / Tumor Cells



Normal Cells



 A₃ Adenosine Receptor (A₃AR)

Targeted therapy, specifically aimed at diseased cells

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Drug Development Pipeline

Indication/Drug	Pre-clinical	Phase I	Phase II	Phase III
Inflammation				
Psoriasis – CF101				In preparation
Rheumatoid Arthritis – CF101				In preparation
Oncology				
Liver Cancer – CF102			On-going	
Sexual Dysfunction				
CF602	On-going			
Ophthalmology				
Glaucoma – CF101			On-going	
Operated by our subsidiary Ophthalix (OTCQB: OPLI)				

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Corporate Partnerships

Regional out-licensing deals - ~\$10 million received to date



[Traded on South Korean Stock Exchange (Ticker: A009290)]

- Exclusive regional license to develop and commercialize CF101 for the treatment of rheumatoid arthritis in Korea
- Up to \$1.5 M in upfront and milestone payments (\$0.5M received to date)
- 7% royalties. Such payments are subject to development and marketing milestones



[Traded on Nasdaq (Ticker: CPHR); TSX: (Ticker: CPH)]

- Exclusive regional license to distribute CF101 for the treatment of rheumatoid arthritis and moderate to severe psoriasis in Canada
- Up to CDN\$3.65M in upfront and milestone payments (CDN\$1.65M received to date)
- 16.5% royalties.

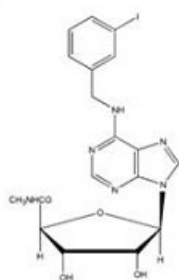
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CF101 – Anti-Inflammatory Effect

Properties

- Highly Selective A₃AR Agonist
- Nucleoside derivative
- Molecular weight - 510.29
- Water insoluble
- Orally bioavailable
- Half life time in blood – 8-9 hours
- Is not metabolized in the body
(secreted unchanged)



Fishman et al. Drug Discovery Today 17:359-366. 2011.

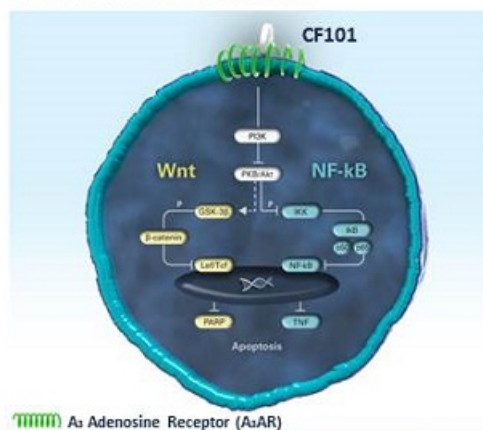
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Anti-Inflammatory Effect

Proof of concept in pre-clinical pharmacology studies:

- Rheumatoid Arthritis
- Osteoarthritis
- Inflammatory Bowel Disease
- Uveitis

Mechanism of Action

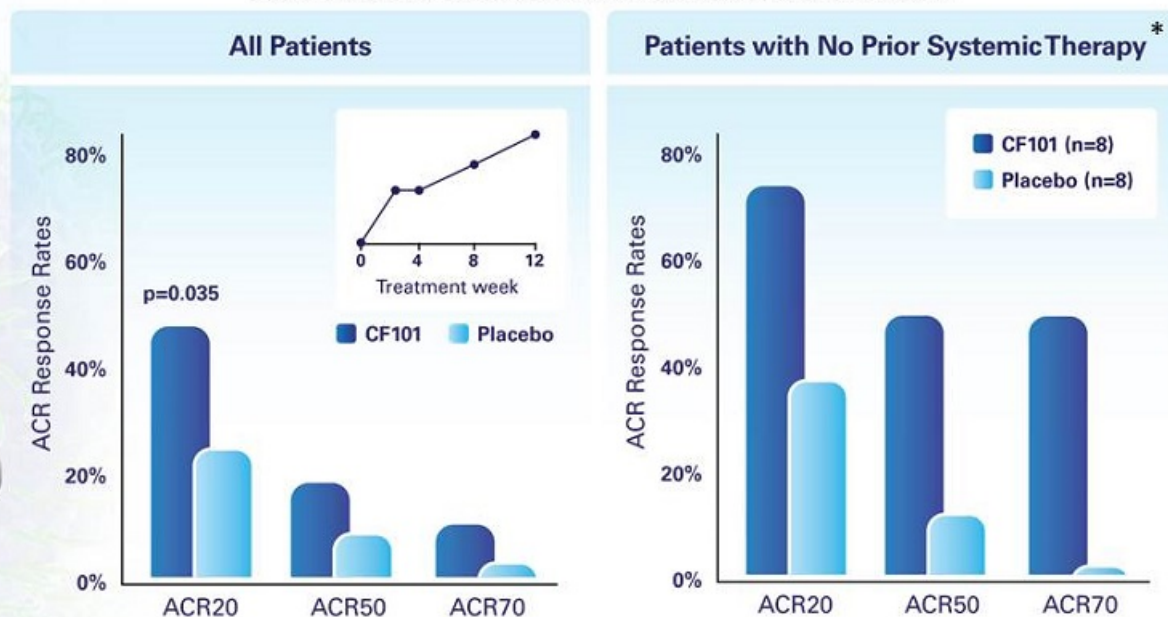


 A₃ Adenosine Receptor (A₃AR)

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Rheumatoid Arthritis - Positive Data from Phase II Study

Phase IIb study, Placebo controlled; 79 patients;
enrolled based on the A3 Adenosine receptor biomarker



A Phase III study design has been completed

*MTX, Biological Drugs

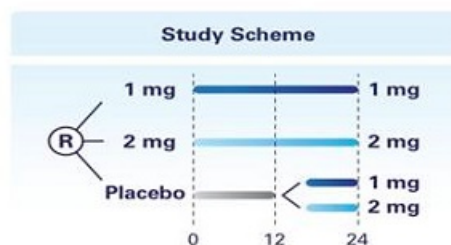
CF101 - Psoriasis

Phase II/III - Study Protocol

- Double-blind, placebo-controlled study to test efficacy of CF101 in 320 patients with moderate-to-severe plaque psoriasis
- 3 arms: 1 mg, 2 mg and of CF101 and placebo
 - All patients receiving placebo were switched to either 1 mg or 2 mg CF101 after 12 weeks
- Study duration initially 24 weeks, subsequently extended to 32 weeks
- Interim analysis after 103 patients

Primary End Point

- PASI 75 after 12 weeks
- Safety parameters

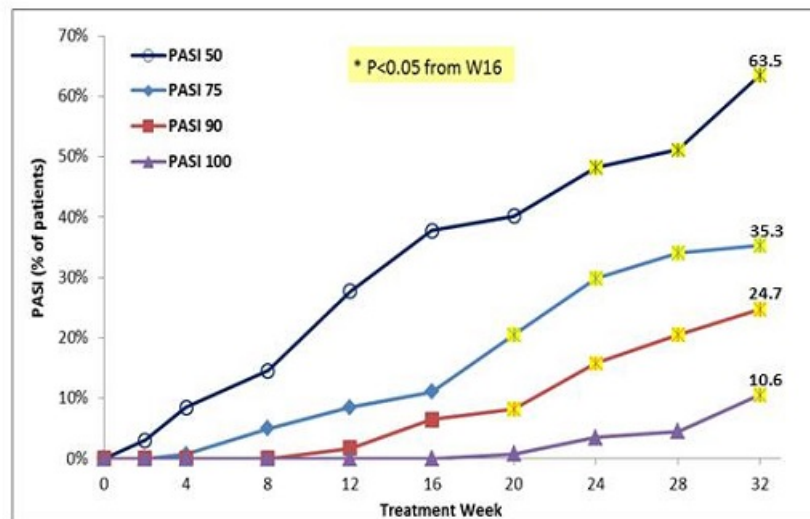


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Psoriasis – Data from Phase II/III Study

The study did not achieve the primary endpoint of PASI 75 at 12 weeks; Excellent safety profile in all tested dosages; Positive linear data on Weeks 12 to 32

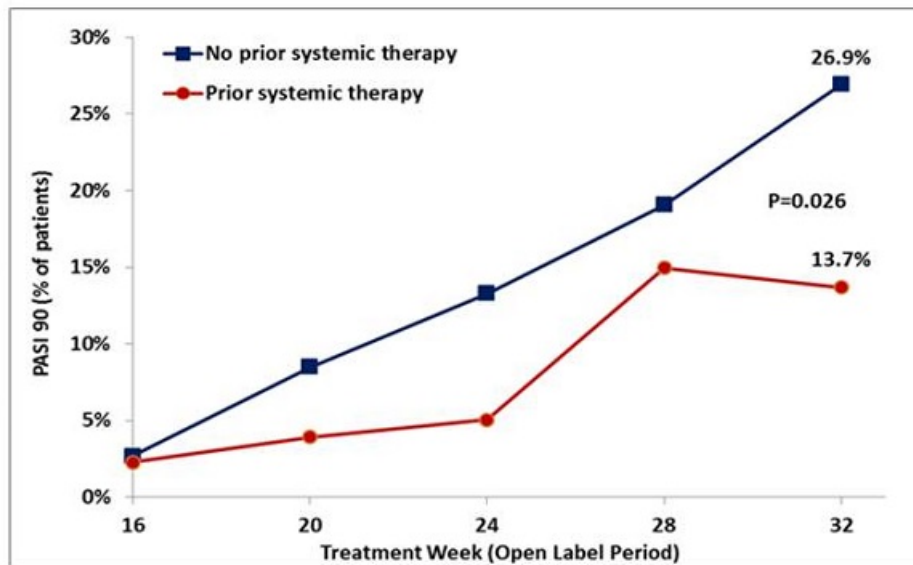
Significant Linear Effect of CF101 on PASI Scores through 32 Weeks of Treatment



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PASI 90 Response in Treatment-Naïve Patients*

Statistically Significant Linear PASI 90 Response



*MTX, Biological Drugs



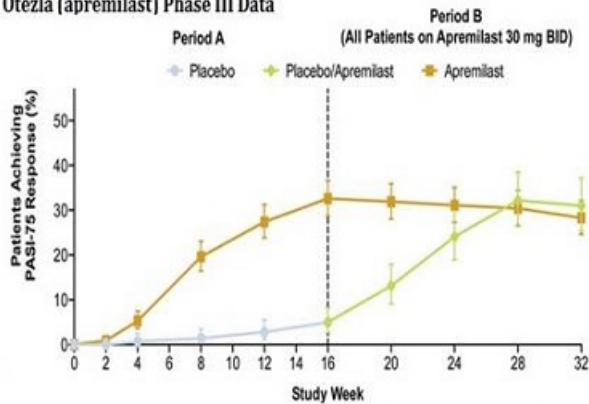
Psoriasis – Positive Linear Data on Weeks 12 to 32

- **PASI 75** - 35.3% by 32 weeks of treatment; linear response
- **PASI mean percent improvement** - 57% ($p < 0.001$); linear from 16 to 32 weeks.
- **PASI 90 and PASI 100** – 24.7% and 10.6%, respectively by 32 weeks of treatment; linear increase.
- **Historical placebo responses** - very rare at PASI 90 and PASI 100.
- **Systemic treatment-naïve patients** - efficacy appears particularly high with PASI 90 scores achieved in 26.9% of patients previously untreated with systemic therapy vs. patients previously treated with systemic therapy ($p < 0.026$).

CF101 Compares Favorably To Celgene's Otezla®

Otezla®

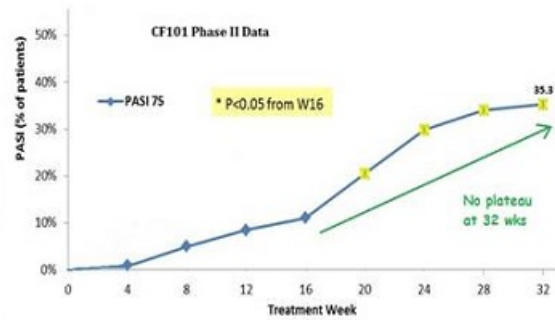
Otezla (apremilast) Phase III Data



Fapp, MD, PhD, K. et al. March 2014; American Academy of Dermatology

CF101

Statistically significant cumulative and linear improvement during weeks 16 to 32.



- Otezla® efficacy plateaus at 16 weeks (PASI-75 ≈ 33%)
- CF101 shows no visible plateau at 32 weeks (PASI-75 = 35.3%)
- Otezla® sales in Q2 2015 were \$90 million, up 49% sequentially (Source: Celgene Q2 2015 press release)
- Analysts think the peak sales for the drug are \$2.3 billion (DRUGANALYST LTD)

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CF101 Compares Favorably To Celgene's Otezla

	PASI Improvement from Baseline	PASI 90	PASI 100
CF101, Can-Fite	57.1% at week 32 no plateau at week 32	24.7% at week 32 no plateau at week 32	10.6% at week 32 no plateau at week 32
Otezla, Celgene	~57% at week 24 start to plateau at week 20	11.4% at week 16 16.7% at week 24	Not analyzed as there were too few participants at week 16
Placebo (historical)	Unknown	0.0%	0.0%

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Phase II/III Safety Data– Comparable to Placebo

	CF101 2 mg BID	Placebo BID
Vital Signs	No significant change	No significant change
ECG	No significant change	No significant change
Clinical Laboratory	No significant change	No significant change
Any Adverse Event (AE)	25.5%	19.6%
Infection AE	6.9%	8.8%
“Related” AE	6.9%	4.1%
Moderate-Severe AE	7.6%	5.4%
Withdrawal due to AE	0.0%	0.7%

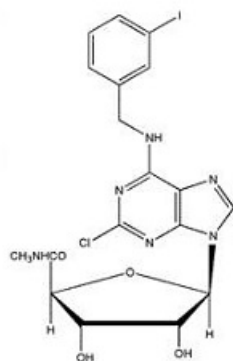
CF101 Continues to Show an Excellent Safety Profile

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CF102 – Anti-Cancer

Properties

- Highly Selective A3AR Agonist
- Nucleoside derivative
- Molecular weight - 544.73
- Water insoluble
- Orally bioavailable
- Half life time in blood – 12 hours

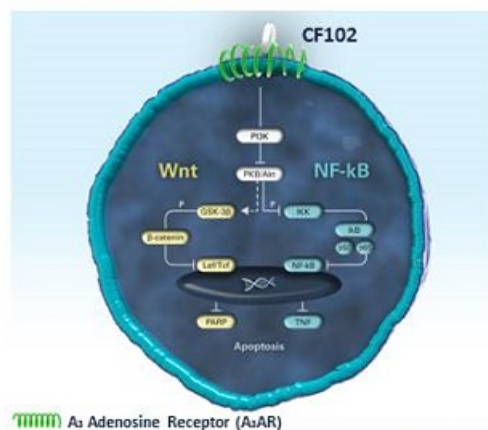


Anti-Cancer Effect

Proof of concept in pre-clinical pharmacology studies:

- Hepatocellular Carcinoma
- Colon Carcinoma
- Prostate Cancer
- Melanoma

Mechanism of Action



A₃ Adenosine Receptor (A₃AR)

We are in discussions with potential partners for regions outside the U.S./EU

Liver Cancer – Phase II Global Study Ongoing

Phase II - Ongoing

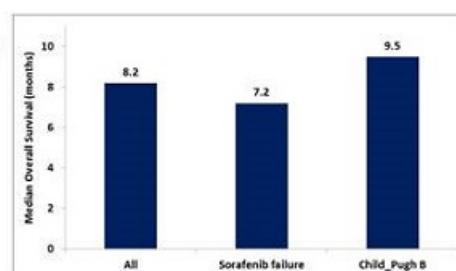
Patient enrolment for a global Phase II study has been initiated and designed as follows:

- Second-Line Treatment
- Advanced Hepatocellular Carcinoma; Child-Pugh B
- 78 patients;
- US, Europe and Israel
- Primary end point: overall survival



Phase I/II Positive Results

- Very favorable safety profile and lack of hepatotoxicity
- Prolongation of survival time
- Regression of skin tumor metastases
- Stable disease (22%)
- Proof of concept for A3AR utilization as a biomarker
- U.S. FDA Orphan Drug Approval (Feb 2012)

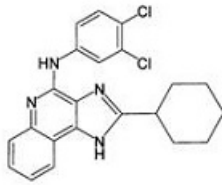


Stemmer et al. The Oncologist, 2012

(NYSE MKT:CANF) (TASE:CFBI)

CF602 – Sexual Dysfunction – A Safe Drug

Chemical Structure



1H-Imidazo[4,5-c]quinolin-4-amine Derivatives

Properties

- A₃AR allosteric modulator
- Molecular weight – 411.34
- Water insoluble
- Orally bioavailable
- Belong to the family of imidazoquinoline derivatives

Current status

- Manufacturing of CF602 to be used in pre-clinical studies has been completed
- Pre-clinical studies – ongoing

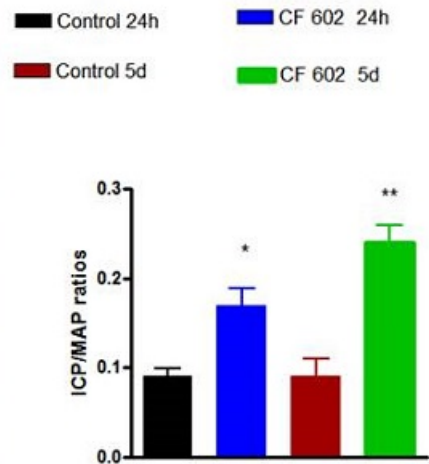
Cohen et al. Mediators of Inflammation. 2015

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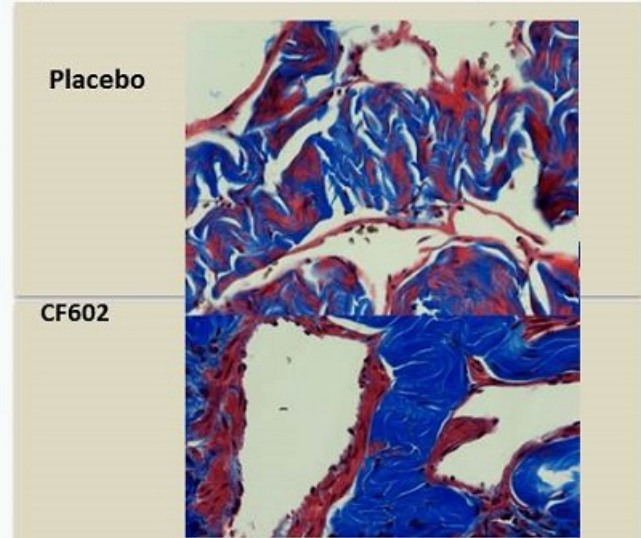
CF602 – Improvement of Erectile Dysfunction

Diabetic Rat Model

Intra-cavernous pressure (ICP)/mean arterial pressure (MAP) ratios



CF602 acts as a vaso-relaxant to promote smooth muscle relaxation and penile erection



Histological evaluation using a Masson Trichrome stain for smooth muscle detection in Corpus Cavernous blood vessels in an erectile dysfunction model in diabetic rats

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Equity Profile

Ticker on NYSE: **CANF**

Ticker on Israeli TASE: **CFBI**

Price of ADR: **\$1.77** (1 ADR = 2 Ordinary Shares)

52 Week Range: **\$1.46 - \$5.83**

Shares Out: **21.3M** Ordinary Shares

Market Capitalization: **~\$20M**





Avg. Trading Volume (30 day): **103,763** ADRs

Cash as of June 30: **\$7,747,000**

As of September 1, 2015

(NYSE MKT:CANF) (TASE:CFBI)

Spotlight on 12 Month Milestones

CF101 – Psoriasis (~\$9B Opportunity)	
Reported Favorable Follow-Up Data from Phase II/III Study in Patients with Psoriasis	
Preparing Clinical Protocol For Phase III Study	H2-2015
CF101 – Rheumatoid Arthritis (~\$38B Opportunity)	
Reported Positive Data From Phase IIb Trial in Treatment-Naïve Patients with RA and High Levels of A ₃ AR Expression	
Submission of Phase III RA Clinical Protocol To IRB (U.S. & EU)	Q4-2015
CF102 – Liver Cancer (~\$2B Opportunity)	
Complete Patient Enrollment in Phase II Study	H1-2016
CF602 – Sexual Dysfunction (~\$2.6B Opportunity)	
Presented Preclinical Data Showing Proof-of-Concept In Animal Model of Erectile Dysfunction	
File U.S. IND / Initial Phase I Study	H1-2016
Ophthalix (~\$3B Opportunity)	
Entered Into Acquisition Agreement With Medical Device Company – Improved Vision Systems, LTD (IVS)	
Report Data From Phase II Study In Glaucoma With CF101	H1-2016

(NYSE MKT:CANF) (TASE:CFBI)

²²
*Sources: Visiongain estimates global psoriasis drug market will be \$9b by 2018 and the global rheumatoid arthritis drug market will be \$38b by 2017; Global Industry Analysts estimates the global liver cancer drug market at \$2b in 2015; GlobalData estimates the global erectile dysfunction drug market at \$2.6b by 2018 and the global glaucoma market to grow to \$3 billion by 2023

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