
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 January 2016

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333-199033 and 333-204795), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 January 11, 2016, Can-Fite BioPharma Ltd. (the “Company”) issued a press release announcing its anticipated clinical milestones for calendar year 2016. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In addition, on January 11, 2016, the Company made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.2 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	Press Release, dated January 11, 2016
99.2	Investor Presentation – January 2016

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 January 11, 2016

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



Can-Fite Announces 2016 Clinical Milestones for its Pipeline of Drugs in Six Indications

- *Phase III trials in rheumatoid arthritis and psoriasis expected to commence in 2016*
 - *Planning Phase II trial for new indication in NASH*
 - *Data expected in Phase II glaucoma trial*
- *Completion of patient enrollment anticipated in Phase II liver cancer trial*

PETACH TIKVA, Israel, January 11, 2015 -- [Can-Fite BioPharma Ltd.](#) (NYSE MKT: CANF) (TASE: CFBI), a biotechnology company with a pipeline of proprietary small molecule drugs being developed to treat inflammatory diseases, cancer and sexual dysfunction, today announced its anticipated clinical milestones for calendar year 2016.

Q1 2016 Rheumatoid Arthritis Phase III EMA Submission for CF101

In the first quarter of 2016, Can-Fite plans to file its Phase III protocol with the European Medicines Agency (EMA) for CF101 in the treatment of rheumatoid arthritis. Initiation of patient enrollment is anticipated in the second or third quarter of 2016. Can-Fite recently filed a trial protocol with the institutional review board (IRB) of Barzilai Medical Center in Israel, one of the planned clinical sites for the international trial to be conducted in Israel, Europe, Canada and the U.S. The Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study will investigate the efficacy and safety of CF101 administered orally twice daily for 16 weeks to patients with active rheumatoid arthritis treated with conventional drugs. The study will have three arms, a 1 mg CF101 dose, a 2 mg CF101 dose, and placebo, given orally twice daily in the form of tablets. Approximately 456 patients are expected to be enrolled in the study. According to Visiongain, the global rheumatoid arthritis market is forecasted to reach \$38.5 billion by 2017.

H1 2016 Psoriasis Phase III EMA Submission for CF101

Can-Fite is now completing the design of its Phase III study protocol for CF101 in the treatment of psoriasis which the Company plans to file with the EMA in the first half of 2016 and anticipates initiating patient enrolment in the fourth quarter of 2016. The Company previously reported positive data from further analysis of its completed Phase II/III study that suggests CF101 as a potential systemic therapy for patients with moderate-severe psoriasis, this despite the study not meeting its primary endpoint. The psoriasis drug market is forecast to grow to \$8.9 billion by 2018, according to estimates of Visiongain.



H1 2016 Liver Cancer Phase II Completion of Patient Enrollment for CF102

Can-Fite anticipates completing enrollment of approximately 78 patients during the first half of 2016, in its Phase II trial for CF102 in the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer. The randomized, double-blind, placebo controlled trial is being conducted in the U.S., Europe and Israel. CF102 received Fast Track Designation from the U.S. FDA as a second line treatment for HCC in patients who have previously received Nexavar (sorafenib). The drug 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. According to Global Industry Analysts the global market for liver cancer was projected to exceed \$2 billion by 2015.

Q2 2016 NASH Phase II Study Protocol Submission to IRBs for CF102

Can-Fite plans to file a Phase II study protocol with IRBs for its first human clinical study of CF102 in the treatment of non-alcoholic steatohepatitis (NASH), a new indication identified by the Company for its liver cancer drug. In November 2015, Can-Fite announced compelling pre-clinical data on CF102 in the treatment of NASH, a disease for which no FDA approved therapies currently exist. By 2025, Deutsche Bank estimates the addressable pharmaceutical market for NASH will reach \$35-40 billion in size.

Q2 2016 Glaucoma Phase II Data Report for CF101

Can-Fite expects data from its Phase II study of CF101 in the treatment of glaucoma to be reported during the second quarter. Enrollment of 88 patients was recently completed in the study which is being conducted in two European countries and Israel by Can-Fite's subsidiary OphthaliX Inc. The treatment market for glaucoma in the seven major markets is estimated to reach approximately \$3 billion by 2023 according to GlobalData and CF101 is one of only a few oral drugs being developed for glaucoma. The market currently consists primarily of generic eye drop drugs. Oral administration is expected to improve patient compliance.

Q4 2016 Sexual Dysfunction IND/Phase I Study Filing with U.S. FDA for CF602

Can-Fite has an active pre-clinical development program for its next generation drug CF602 in the treatment of sexual dysfunction and is currently developing a working plan to file an investigational new drug (IND) application with the U.S. FDA for a Phase I study during the fourth quarter of 2016. Can-Fite received positive pre-clinical data from experimental animal models demonstrating that CF602 improved sexual dysfunction in a dose dependent manner. GlobalData estimates the value of the erectile dysfunction therapeutic market to be approximately \$2.6 billion by 2018 with few drugs on the market which includes Viagra, Cialis and Levitra.

"We are very encouraged by the clinical and preclinical data from each of our drugs to date which indicate their efficacy across six major indications. We are moving towards initiating pivotal Phase III trials in two autoimmune diseases. As we look forward to announcing Phase II results for glaucoma and completing Phase II enrollment for liver cancer, we are preparing to enter human clinical studies in two new indications, NASH and sexual dysfunction. We expect 2016 will be a very active year," stated Can-Fite CEO Dr. Pnina Fishman.



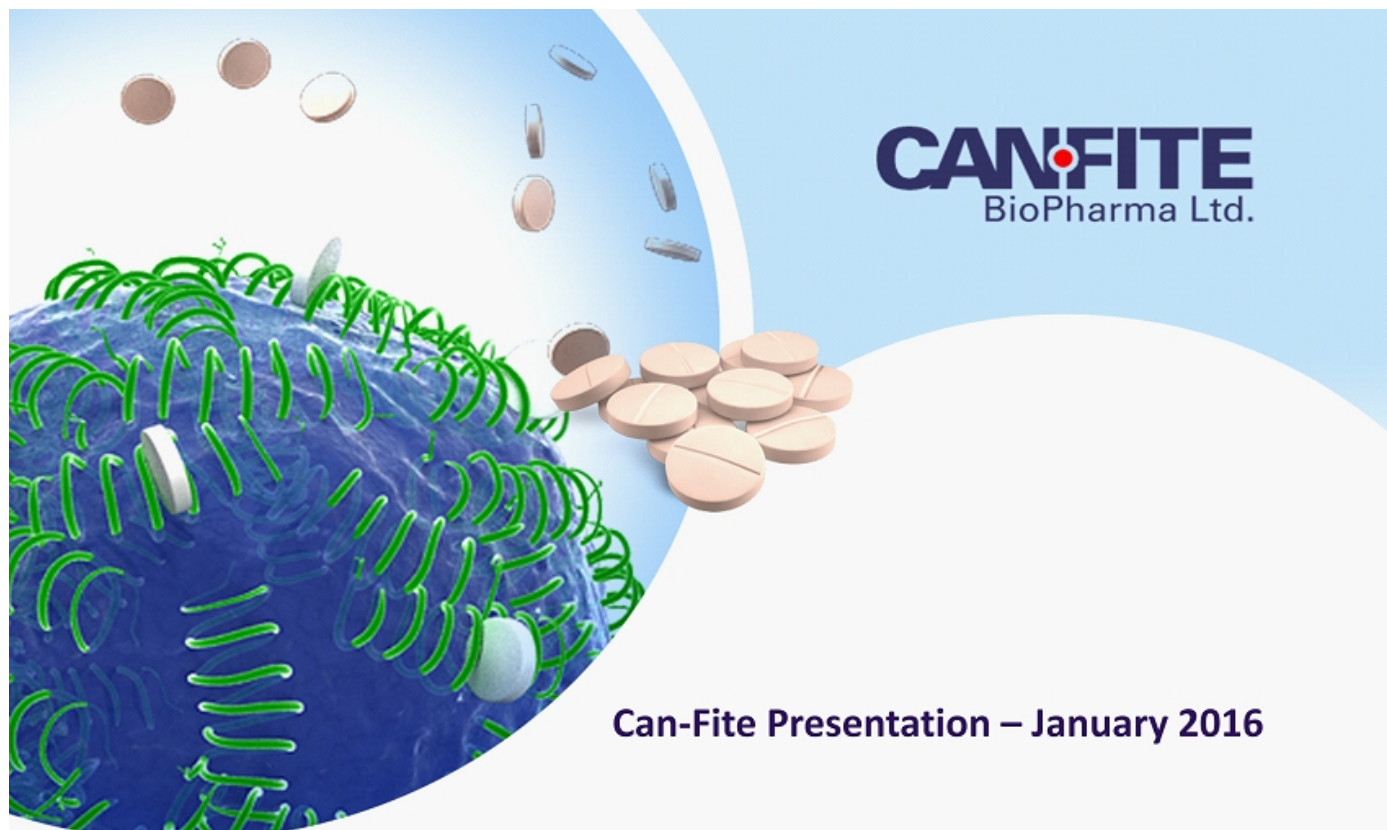
About Can-Fite BioPharma Ltd.

Can-Fite BioPharma Ltd. (NYSE MKT: CANF) (TASE: CFBI) is an advanced clinical stage drug development Company with a platform technology that is designed to address multi-billion dollar markets in the treatment of cancer, inflammatory disease and sexual dysfunction. The Company is preparing for a Phase III CF101 trial for rheumatoid arthritis and is preparing its protocol for its Phase III psoriasis clinical trial. Can-Fite's liver cancer drug CF102 is in Phase II trials and has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for hepatocellular carcinoma by the U.S. Food and Drug Administration. CF102 has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. The Company's CF602 has shown efficacy in the treatment of erectile dysfunction. Can-Fite has initiated a full pre-clinical program for CF602 in preparation for filing an IND with the U.S. FDA in this indication. These drugs have an excellent safety profile with experience in over 1,200 patients in clinical studies to date. For more information please visit: www.can-fite.com.

Forward-Looking Statements

This press release may contain 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, 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 TASE. In addition, Can-Fite operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. Can-Fite does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise.

Contact
Can-Fite BioPharma
Motti Farbstein
info@canfite.com
+972-3-9241114



CANFITE
BioPharma Ltd.

Can-Fite Presentation – January 2016

Small Molecules For Big Clinical Needs™

(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

Proprietary Core Technology

- Advanced clinical stage drug development company with a compelling platform technology
- Several small molecule drug products in Phase II and Phase III clinical studies

Financial Summary

- Cash as of September 30: \$14.5M with additional ~\$4.8M raised in October 2015
- Listed on Tel-Aviv Stock Exchange (CFBI) and NYSE MKT (CANF)
- Price per ADR* traded on NYSE MKT = \$3.00 (as of 12/29/15)
- Market Cap = \$42 MM (as of 12/29/15)

*1 ADR = 2 Ordinary Shares

Operations

- Headquarters & Discovery Labs – Petach-Tikva, Israel
- Drug Development & Clinical Operations – Boston, USA

(NYSE MKT:CANF) (TASE:CFBI)

Investment Highlights

Innovative Technology for the Treatment of Inflammation & Cancer

- **Selective therapeutic target**, highly expressed on pathological but not normal body cells
- **Strong intellectual property** protection (13 patent families)
- **Advanced clinical studies** - Phase II and Phase III

Small Molecule Drugs in Advanced Clinical Development Stages

- **CF101** - Psoriasis & Rheumatoid Arthritis – Preparation for **Phase III**
- **CF102** - Liver Diseases - Hepatocellular Carcinoma (HCC) in **Phase II**, NASH Preparation for **Phase II**
- **CF602** - Sexual Dysfunction - For patients that cannot use approved products - Preparation for **Phase I**
- **CF101** – Glaucoma - OphthaliX (82% -owned subsidiary) **Phase II**

2016 Expected Compelling News Flow

- **Rheumatoid Arthritis** Phase III trial initiation – Expected Q2/Q3 2016; \$38B Market
- **Psoriasis** Phase III – Trial protocol submission to EMA expected in H1 2016; \$9B Market
- **Glaucoma** Phase II trial – Expect to report data in Q2 2016; \$3B Market
- **Liver Cancer** Phase II trial – Completion of patient enrollment expected in H1 2016; \$2B

Strong Cash Position & Opportunities to Out-License Products Globally

- Regional out-licensing deals; ~ \$10M already received

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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



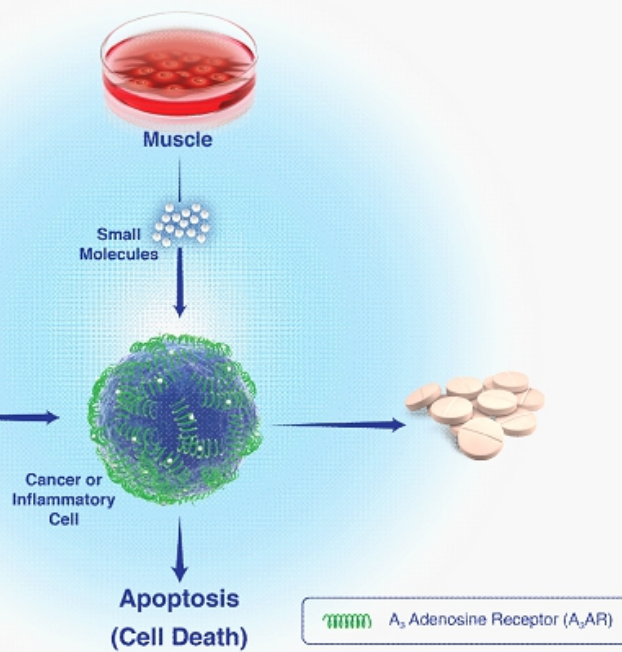
[Traded on Nasdaq (Ticker: CPHR); TSX: (Ticker: CPH)]

- 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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From Concept to Technology

Why Cancer Does Not Metastasize to Muscle?



Company platform technology mimics natural body mechanism to combat cancer and inflammation

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Platform Technology

Therapeutic Target

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

Drug product

- Small molecules
- Orally bioavailable drugs

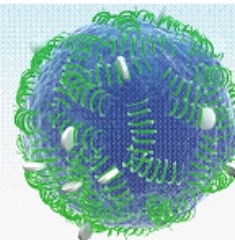
Therapeutic Effect

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

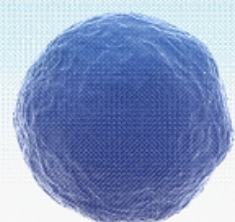
A₃AR is utilized as Predictive Biomarker

- Utilized 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

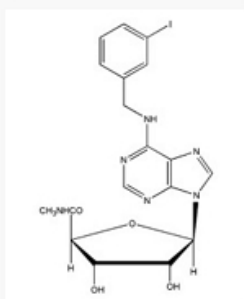
Indication/Drug	Pre-clinical	Phase I	Phase II	Phase III
Inflammation				
Psoriasis - CF101			In preparation	
Rheumatoid Arthritis - CF101			EMA Submission	
Oncology/Liver Diseases				
Liver Cancer - CF102			On-going	
NASH - CF102			In preparation	
Sexual Dysfunction				
CF602		On-going		
Ophthalmology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

(NYSE MKT:CANF) (TASE:CFBI)

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.

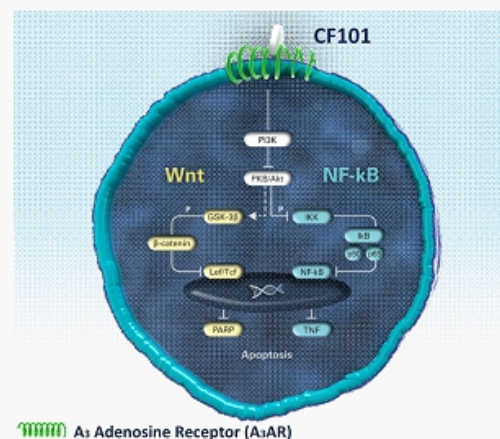
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Anti-Inflammatory Effect

Proof of concept in pre-clinical pharmacology studies:

- Rheumatoid Arthritis
- Osteoarthritis
- Inflammatory Bowel Disease
- Uveitis

Mechanism of Action

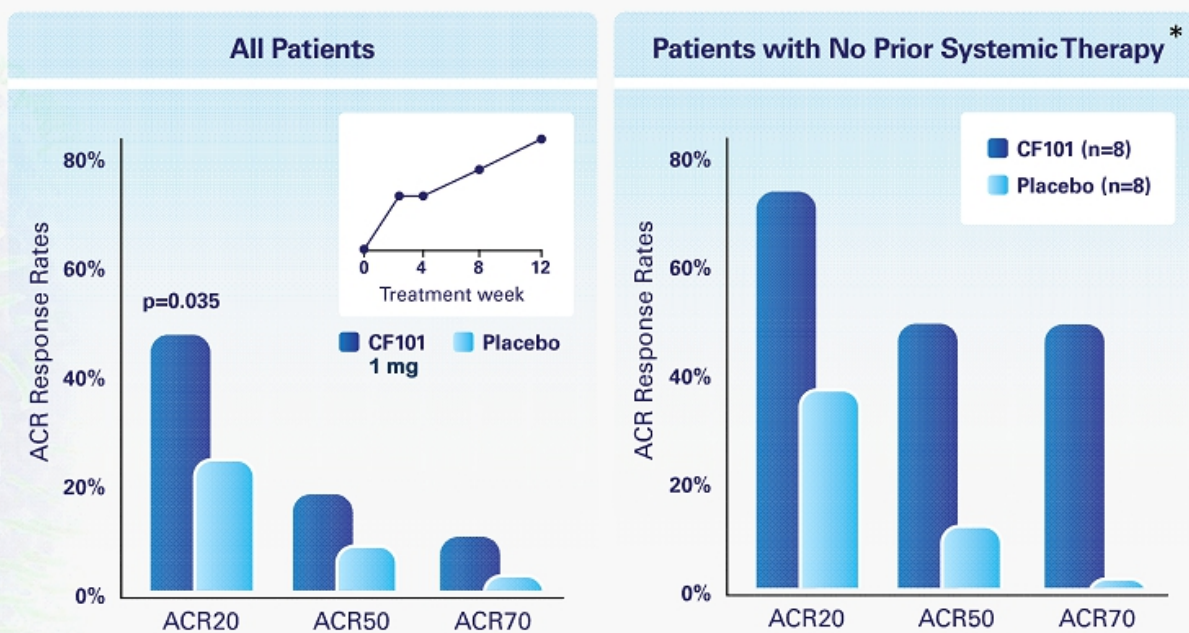


A₃ Adenosine Receptor (A₃AR)

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Rheumatoid Arthritis - Positive Data from Phase II Study

Phase IIb study, Placebo controlled; 79 patients



*MTX, Biological Drugs

Rheumatoid Arthritis – Phase III Study

Phase III - Study Protocol

- A Phase III trial to evaluate the efficacy and safety of CF101 when added to conventional therapy in the treatment of rheumatoid arthritis
- 3 arms: 1 mg & 2 mg of CF101 and placebo
- Number of patients planned: 456; 152 per study arm
- Study duration: 16 weeks
- Primary End Point: ACR20 at 16 weeks of treatment

Regulatory Status

- Successful meeting with the Medical Products Agency (MPA) in Sweden
- IRB submission of Phase III protocol in Israel
- EMA submission expected in Q1 2016

*MTX, Biological Drugs

CF101 - Psoriasis

Phase II/III - Study Protocol

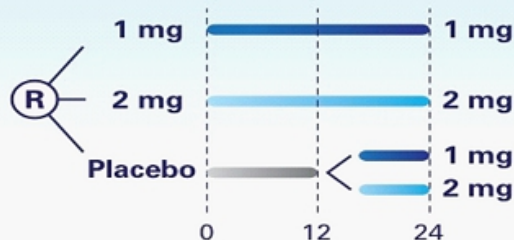
- Double-blind, placebo-controlled study to test efficacy of CF101 in 320 patients with moderate-to-severe plaque psoriasis
- 3 arms: 1 mg & 2 mg of CF101 and placebo
 - All patients receiving placebo were switched to either 1 mg or 2 mg CF101 after 12 weeks
- Study duration initially 24 weeks, subsequently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

Primary End Point

- PASI 75 after 12 weeks
- Safety parameters



Study Scheme



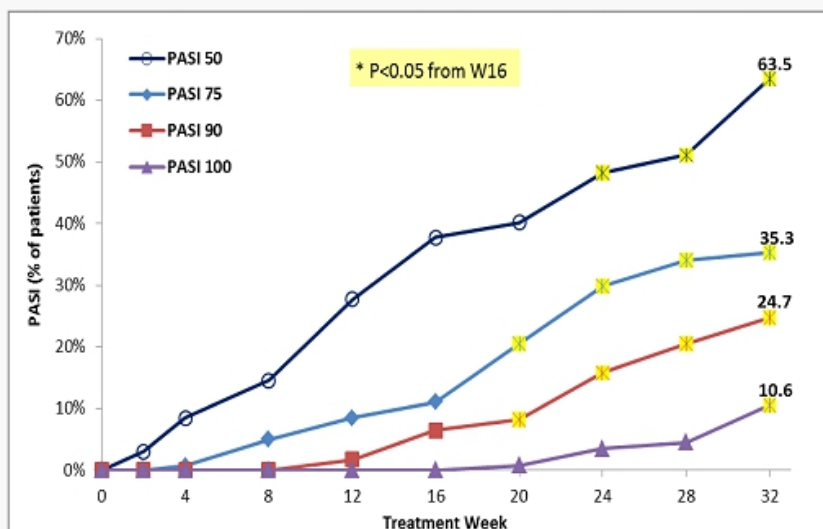
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Psoriasis – Data from Phase II/III Study

- 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

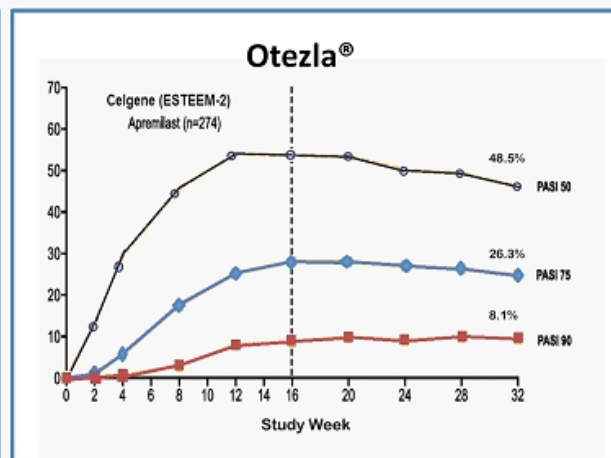
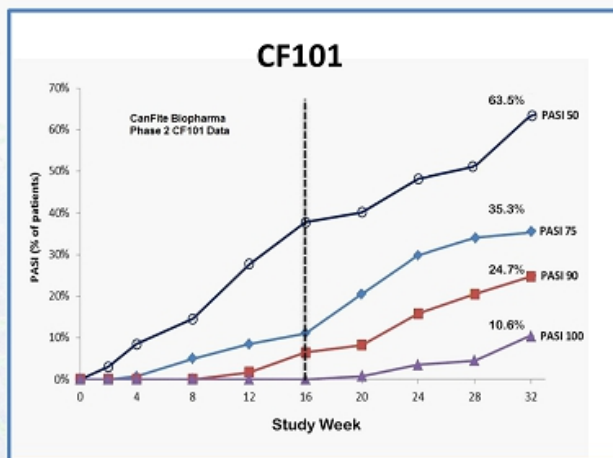
Significant Linear Effect of CF101 on PASI Scores through 32 Weeks of Treatment



Phase III protocol submission to EMA in H1 2016

(NYSE MKT:CANF) (TASE:CFBI)

CF101 Compares Favorably To Celgene's Otezla®



- Otezla® efficacy plateaus at 16 weeks (PASI-75 ≈ 33%)
- CF101 shows no visible plateau at 32 weeks (PASI-75 = 35.3%)
(2 Different Studies)

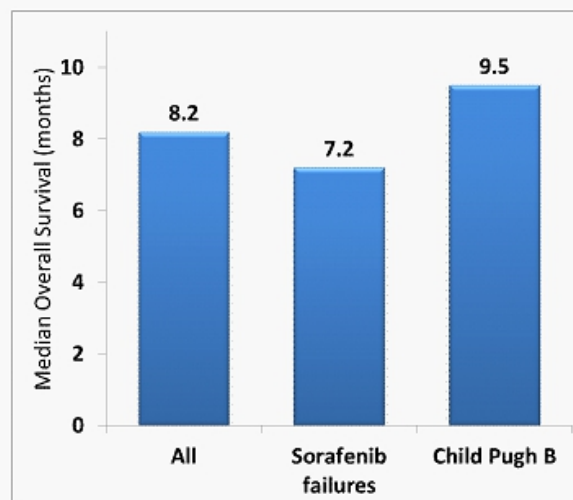
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Liver Cancer – Positive Data from Phase I/II Study

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 Fast Track & Orphan Drug Designation



Stemmer et al. The Oncologist, 2012

Market Opportunity

- Significant unmet need – there is only one drug registered to treat primary liver cancer patients - Nexavar® (sorafenib).
- According to Global Industry Analysts, the global market for liver cancer drugs was projected to exceed \$2 billion in 2015. Nexavar® annual sales, as reported by Bayer, were €773 million in 2014.

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Liver Cancer – Phase II Global Study Ongoing

Phase II - Study Protocol

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



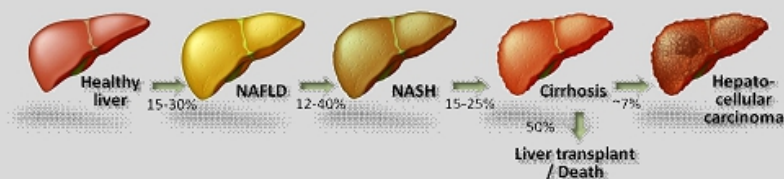
Study Status

- Regulatory approvals to commence Phase II study were received in the US, Europe and Israel
- Patient enrollment for a global Phase II study has been initiated
- Completion of patient enrollment in Phase II study expected in H1 2016

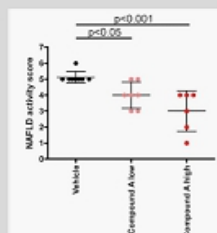
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CF102 for the Treatment of NASH

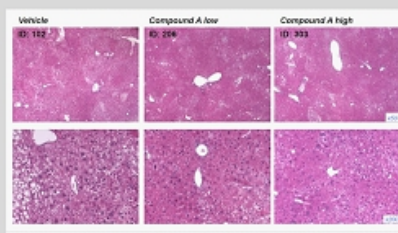
Non-alcoholic fatty liver disease (**NAFLD**), the most common form of liver disorder in the US, is developed into "fatty liver", causing inflammation, designated as **NASH**



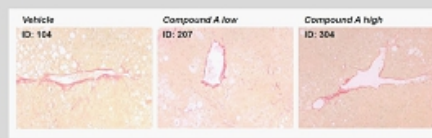
CF102 markedly improved liver function & pathology in NAFLD and NASH



CF102 reduces NAFLD Activity Score (NAS)



Significant decrease in steatosis, ballooning and lobular inflammation



A decrease in plasma ALT and triglyceride levels

Phase II Study is in Preparation

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CF602 – Sexual Dysfunction – A Safe Drug

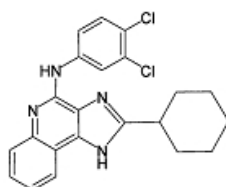
Properties

- 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

Chemical Structure



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

Cohen et al. Mediators of Inflammation. 2015

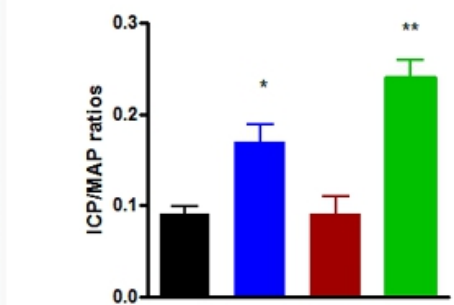
(NYSE MKT:CANF) (TASE:CFBI)

CF602 – Improvement of Erectile Dysfunction

Diabetic Rat Model

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

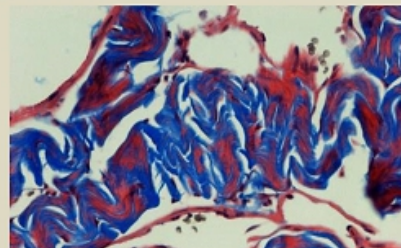
■ Control 24h ■ CF 602 24h
■ Control 5d ■ CF 602 5d



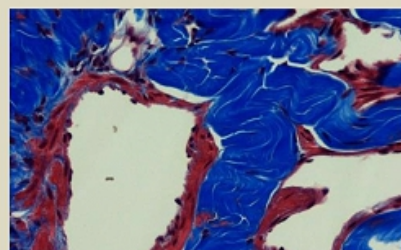
CF602 acts as a vaso-relaxant

to promote smooth muscle relaxation and penile erection

Placebo



CF602



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

Preparatory work for a Phase I study

Spotlight on 12 Month Milestones

CF101 – Rheumatoid Arthritis (~\$38B Opportunity)	
Phase III EMA Submission	Q1-2016
Phase III Trial Initiation	Q2/Q3-2016
CF101 – Psoriasis (~\$9B Opportunity)	
Phase III EMA Submission	H1-2016
Phase III Trial Initiation	Q4 - 2016
CF102 – Liver Cancer (~\$2B Opportunity)	
Complete Patient Enrollment in Phase II Study	H1-2016
CF102 – NASH (~\$35B Opportunity)	
Phase II IRB submission	Q2-2016
CF602 – Sexual Dysfunction (~\$2.6B Opportunity)	
File U.S. IND / Phase I Study IRB Submission	Q4-2016
Ophthalix (~\$3B Opportunity)	
Report Data From Phase II Study In Glaucoma With CF101	Q2-2016

(NYSE MKT:CANF) (TASE:CFBI)

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*Sources: Vislangain estimates global psoriasis drug market will be \$9 b by 2018 and the global rheumatoid arthritis drug market will be \$38 b by 2017; Global Industry Analysts estimates the global liver cancer drug market at \$2 b in 2015; GlobalData estimates the global erectile dysfunction drug market at \$2.6 b by 2018 and the global glaucoma market to grow to \$3 billion by 2023; Deutsche Bank puts the peak market for NASH therapies at \$35 billion to \$40 billion by 2025.

CANFITE
BioPharma Ltd.