
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 2019

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): ____

On September 6, 2019, Can-Fite BioPharma Ltd. updated its corporate presentation that it intends to use in conferences and meetings with investors from time to time. A copy of the presentation is furnished with this Report of Foreign Private Issuer on Form 6-K as Exhibit 99.1 and is incorporated herein by reference.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Can-Fite Presentation dated September 2019

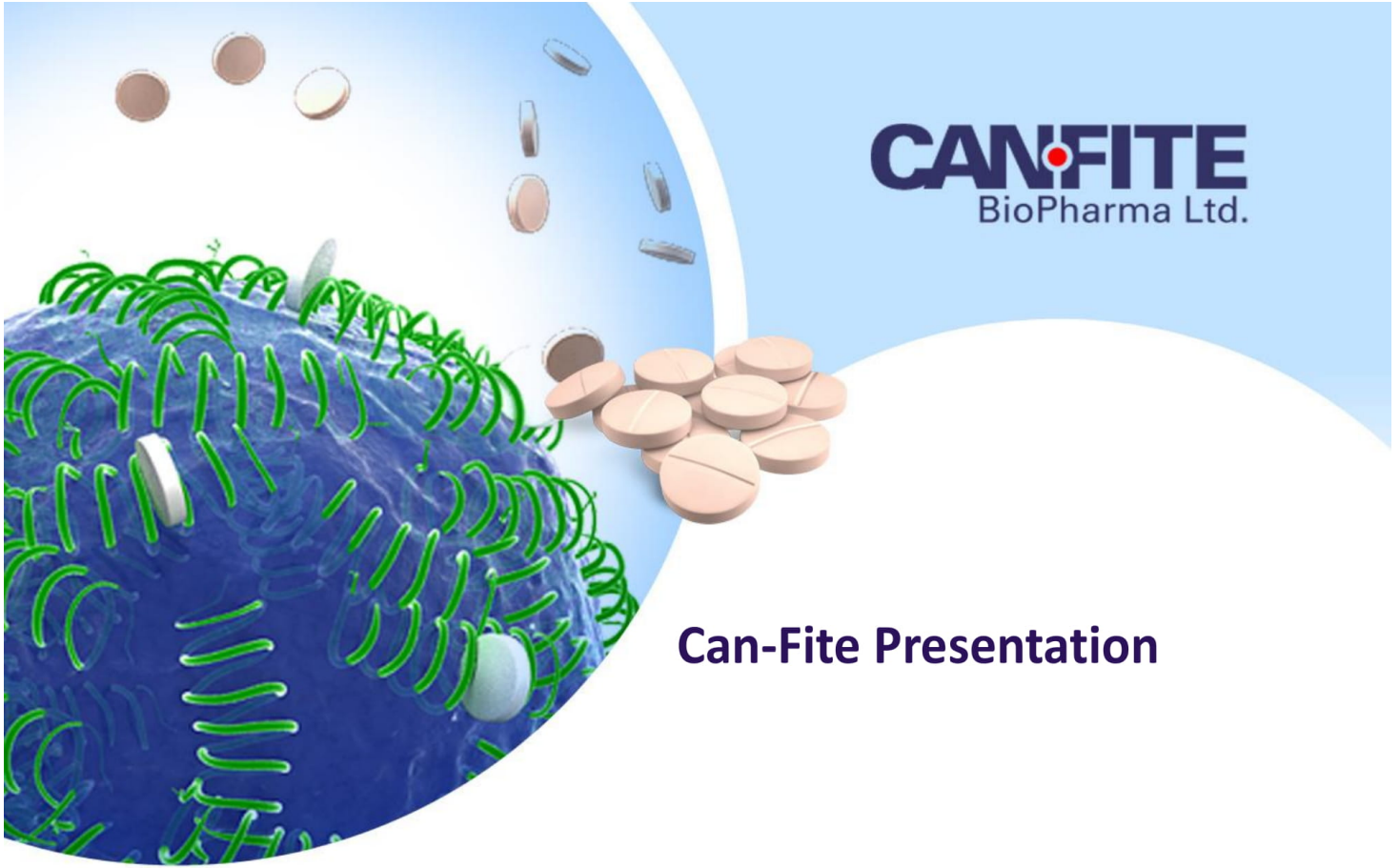
SIGNATURES

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.

Date: September 6, 2019

Can-Fite BioPharma Ltd.

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



CANFITE
BioPharma Ltd.

Can-Fite Presentation

September 2019

Small Molecules For Big Clinical Needs™

(NYSE American: CANF) (TASE:CFBI)

Forward Looking Statement

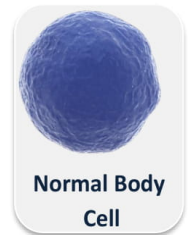
- This presentation contains forward-looking statements, about Can-Fite’s expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are “forward looking statements”.
- 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. 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 known and unknown risks, uncertainties and other factors that may cause Can-Fite’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; uncertainties regarding the hostile takeover attempts of Capital Point and the related litigation; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the “Risk Factors” section of Can-Fite’s Annual Report on Form 20-F filed with the SEC on March 28, 2018 and other public reports filed with the SEC and in its periodic filings with the TASE.
- Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

(NYSE American: CANF) (TASE:CFBI)

Company Profile

Proprietary Core Technology

- Advanced clinical stage drug development company with a compelling platform technology
- Small molecule drug products in Phase II and Phase III clinical studies; covered by 13 Patent Families



Financial Summary

- Cash: ~\$8.2 M as of 06/30/2019
 - Listed on NYSE American (CANF) and Tel-Aviv Stock Exchange (CFBI)
 - Price per ADR* traded on NYSE American= \$2.45 (as of 08/30/2019)
 - ~3.3 M ADRs outstanding; ~ 100 M ordinary shares outstanding
- *1 ADR = 30 Ordinary Shares

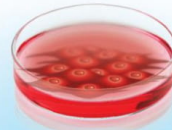
Operations

- Highly experienced management, clinical and regulatory team
- Leading KOLs serve on CAB
- Successful corporate partnerships and licensing deals

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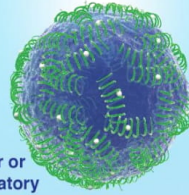
From Concept to Technology

Why Cancer Does Not Metastasize to Muscle?



Muscle

Small Molecules



Cancer or Inflammatory Cell

Apoptosis
(Cell Death)



 A₃ Adenosine Receptor (A₃AR)

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

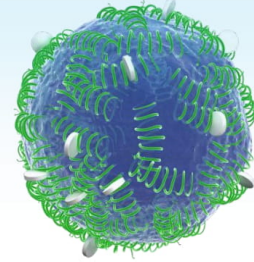
Therapeutic Effect

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

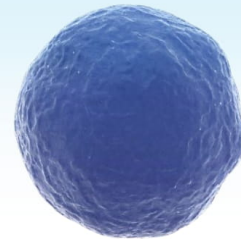
A₃AR is utilized as a Predictive Biomarker

- 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







Drug	Pre-clinical	Phase I	Phase II	Phase III	Market
Piclidenoson					
• Rheumatoid Arthritis				Ongoing	~\$35B
• Psoriasis				Ongoing	~\$11.4B
Namodenoson					
• Liver Cancer			Preparatory work for Phase III		~\$3.8B
• NASH			Phase II Results Q4/2019		~\$35B
CF602					
• Erectile Dysfunction		Ongoing			~\$3.2B

*Sources: Visiongain estimates global psoriasis drug market will be \$11.4bB by 2020 and the global rheumatoid arthritis drug market will be \$34.6B by 2020; DelveInsight estimates the HCC drug market at \$3.8B in 2027; Grand View Research estimates the global erectile dysfunction drug market at \$3.2B by 2022; Deutsche Bank puts the peak market for NASH therapies at \$35B to \$40B by 2025.

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Corporate Partnerships: Out-licensing deals

~\$18 million* upfront and milestone payments received to date for licensing and distribution deals

Licensing Partner	Drug	Indication	Region
	Piclidenoson	RA & Psoriasis	Canada
	Piclidenoson	RA & Psoriasis	Spain, Austria Switzerland
	Piclidenoson & Namodenoson	RA, Psoriasis, Liver Cancer & NASH	China, Hong Kong, Macau, Taiwan
	Piclidenoson	RA	South Korea
	Namodenoson	Liver Cancer & NASH	South Korea
	Piclidenoson	Psoriasis	South Korea

Potential future milestones may trigger additional milestone payments & royalties

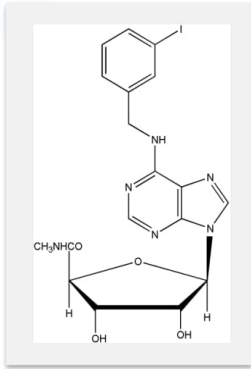
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\$8.5M was from a license with a Japanese company, SKK; the license was terminated due to SKK's strategic change of focus to indications not related to autoimmune diseases

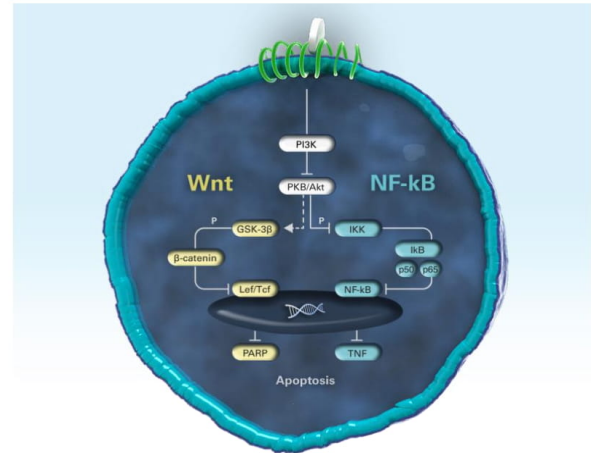
Piclidenoson – Anti-Inflammatory Drug



Piclidenoson

Rheumatoid Arthritis & Psoriasis

Mechanism of Action

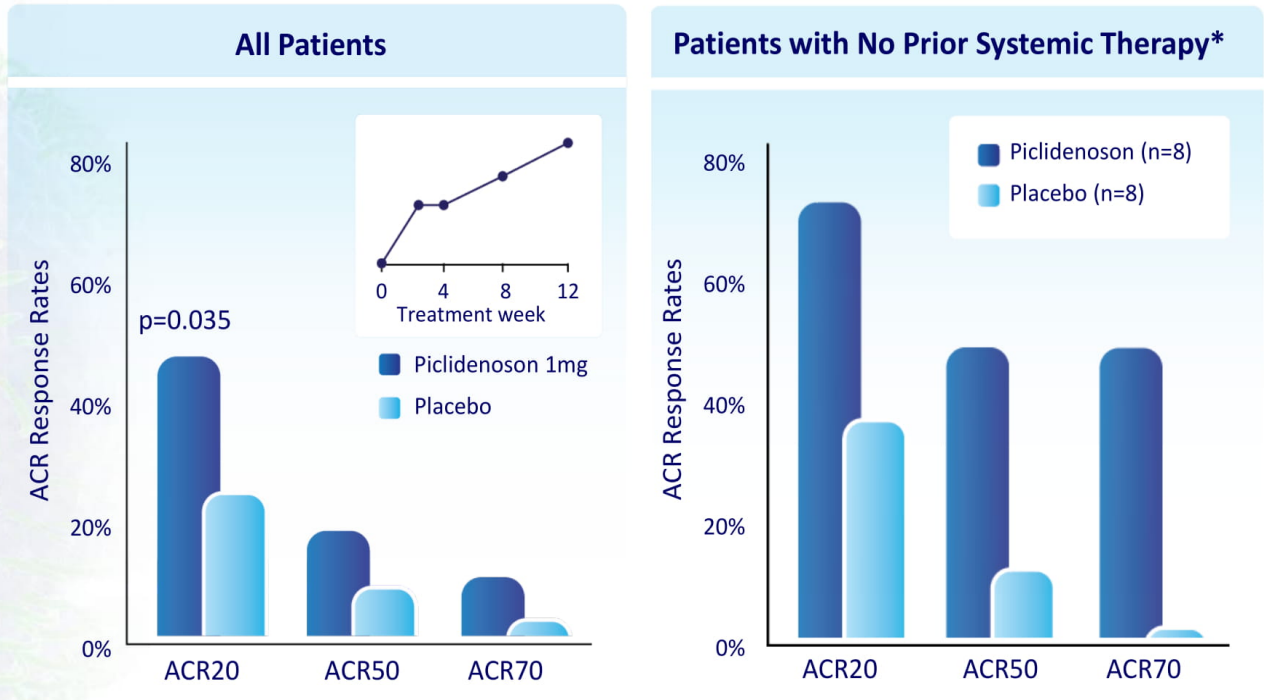


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Rheumatoid Arthritis - Phase IIb Data

Phase IIb study, Placebo controlled; 79 patients – Positively concluded

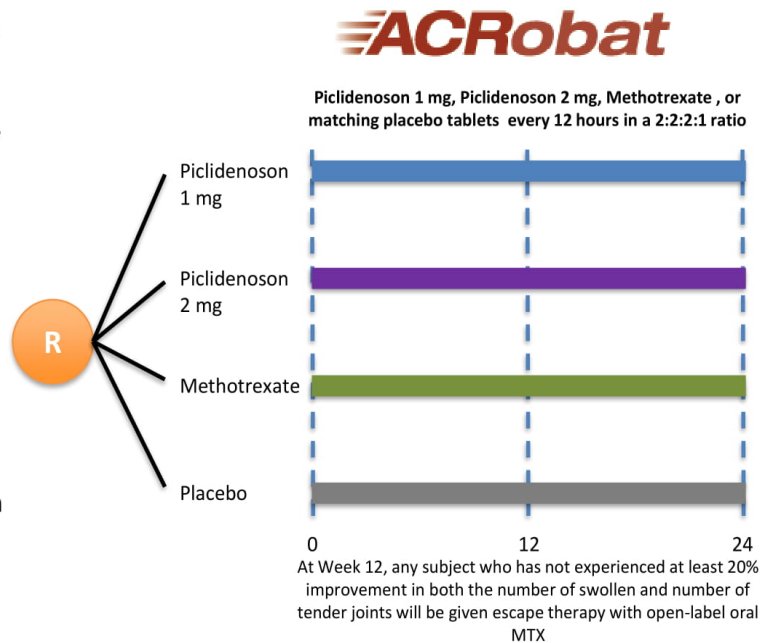


*MTX, Biological Drugs

Rheumatoid Arthritis - Phase III Study Ongoing

*ACRobot – Can-Fite’s Phase III clinical study is designed to establish Piclidenoson as non-inferior to MTX in newly diagnosed patients with moderate-to-severe RA
This Protocol is in Agreement with EMA*

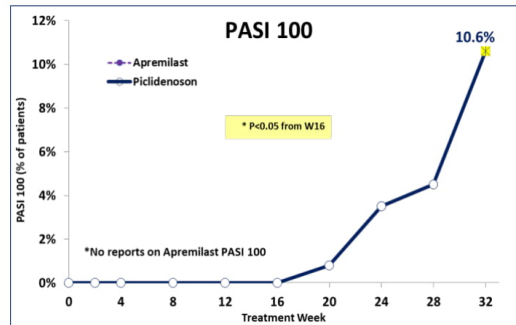
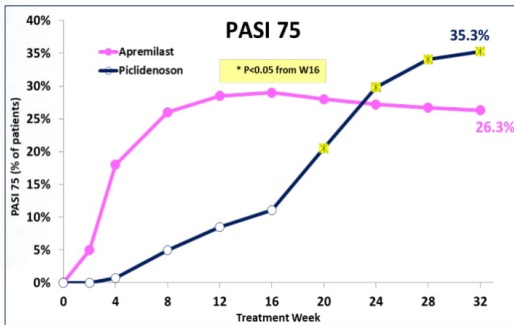
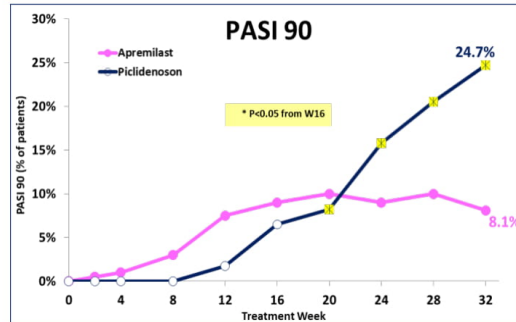
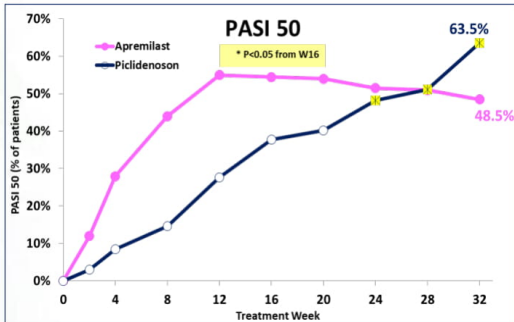
- Randomized, double-blind, active and placebo-controlled
- 500 patients to be enrolled in Europe, Canada and Israel
- Primary endpoint will be Disease Activity Score (DAS) of Low Disease Activity (LDA) at week 12
- Secondary endpoints will include proportion of subjects achieving DAS remission; 24 week total duration
- Correlation between A3AR expression and response to Piclidenoson will be analyzed
- Patient enrollment ongoing



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Psoriasis Phase II/III Data vs. Celgene's Otezla*

- Phase II/III study did not achieve the primary endpoint of PASI 75 at 12 weeks
- Otezla® sales were \$1.3 billion in 2017, 26% increase over 2016¹
- Peak Otezla® sales estimated at \$2.35 billion in 2020²
- Phase II/III study showed that at weeks 24 and 32, Piclidenoson's efficacy as measured by PASI compares well to Otezla® and this is the basis for the current Phase III study



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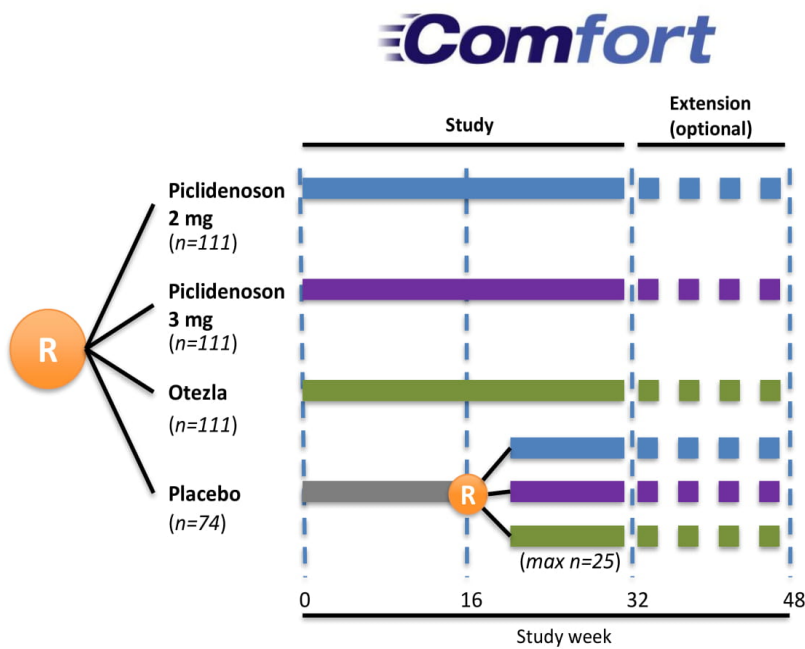
Sources: 1) Celgene 2017 annual report 2) DrugAnalyst, Ltd.

*Comparisons are derived from reported Otezla Phase 3 data vs. Piclidenoson Phase 2 data and are not an actual head-to-head clinical trial. If this were a head-to-head clinical trial, outcomes may be different.

Psoriasis Phase III Study - Ongoing

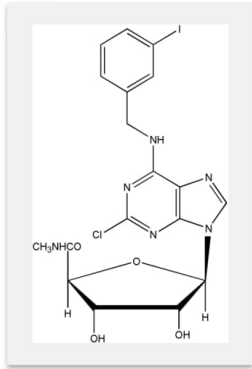
*Comfort – Phase III clinical study is designed to establish Piclidenoson superiority vs. placebo and non-inferiority vs. Otezla in patients with moderate-to-severe Plaque Psoriasis
This Protocol is in Agreement with EMA*

- Randomized, double-blind, active and placebo-controlled
- 407 patients to be enrolled in Europe, Canada and Israel
- Primary endpoint is PASI 75 at week 16 vs. placebo
- Secondary endpoints include non-inferiority vs. Otezla at week 32
- Patients will be selected to the study based on over expression of the A3AR biomarker
- 32 week total duration; optional extension to 48 week



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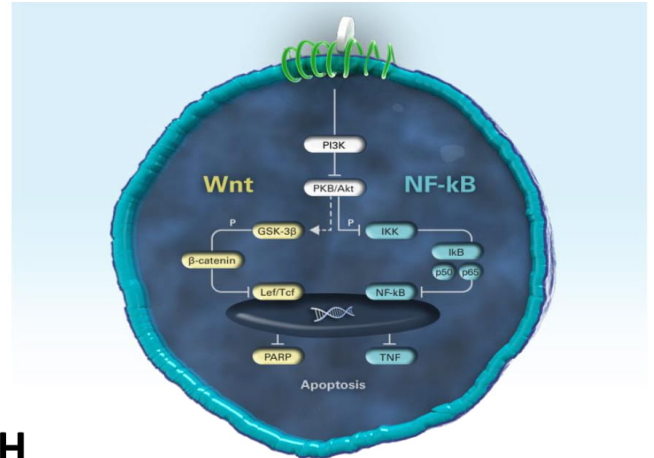
Namodenoson – Liver Disease Drug



Namodenoson

Advanced Liver Cancer & NASH

Mechanism of Action



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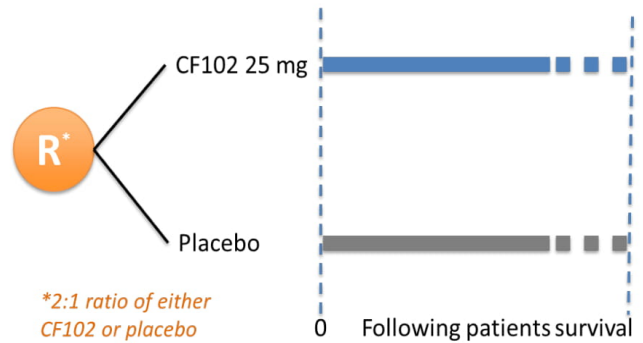
Phase II Study – Advanced Liver Cancer

Phase II - Study Protocol

- Second-Line Treatment
- Advanced Hepatocellular Carcinoma; Child-Pugh B
- 78 patients
- US, Europe and Israel
- Primary end point: overall survival
- Patient enrollment completed August 2017

Regulatory Status

- FDA and EMA have granted **Orphan Drug** status
- FDA granted **Fast Track** status as a second line treatment



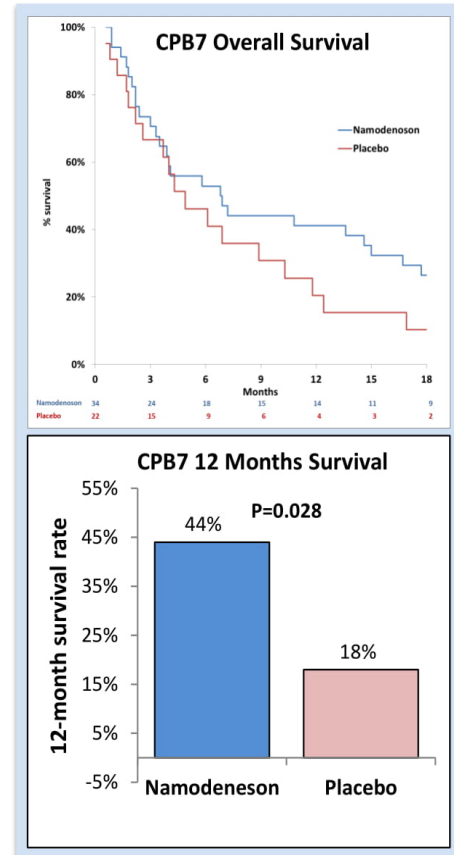
Phase II – Advanced Liver Cancer Results

Phase II Data - Summary

- While the study (78 patients) did not achieve its primary endpoint, it did achieve superiority in survival in the largest subpopulation of CPB7, 56 patients - 6.8 month median overall survival vs. 4.3 months for placebo
- CPB7 group treated with Namodenoson had 44% of patients treated with Namodenoson completed at least 12 months of treatment vs. 18%
- Partial response of 9% has been achieved in the Namodenoson treated group vs. 0% in the placebo group
- Favorable safety profile and lack of hepatotoxicity

Regulatory Status:

Preparatory work for a pivotal Phase III Study

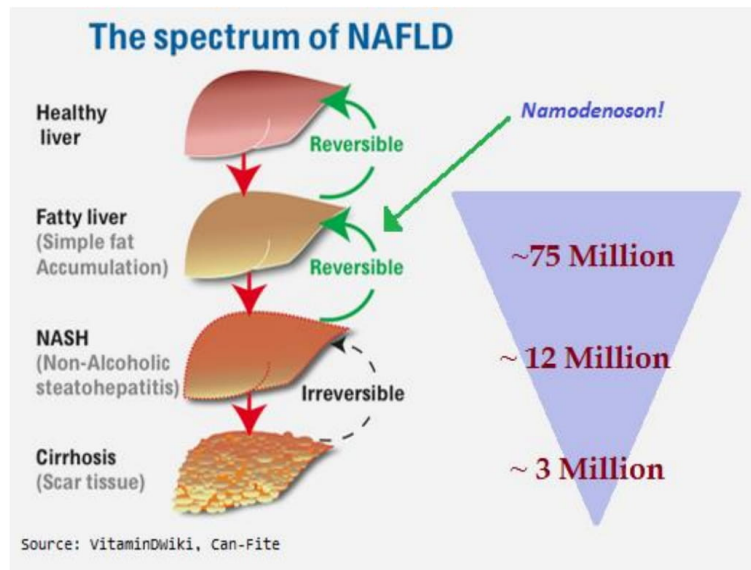


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Namodenoson for the Treatment of NASH

“America’s Greatest Health Risk” – *Scientific American*, 2015

- ✓ 17% - 33% Prevalence of NAFLD in the U.S.¹
- ✓ 2-5% of U.S. Population has NASH²
- ✓ 3rd Leading Cause of Liver Transplant in U.S. & on Trajectory to Become Leading Cause³
- ✓ \$35-40 Billion Market by 2025⁴



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Sources: 1) Study published in Hepatology, 2) NIH, 3) Study published in Gastroenterology, 4) Deutsche Bank

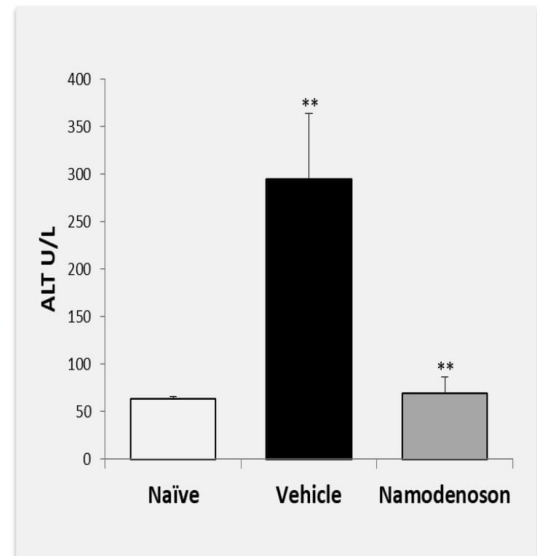
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NASH – Excellent Pre-clinical Data

Namodenoson markedly improved liver function & pathology in NASH experimental models (STAM & CCL4)

- ✓ **Anti - inflammatory** - Namodenoson reduces NAFLD Activity Score (NAS) in STAM model
- ✓ **Anti - Fibrotic effect** - in vitro and in the CCL4 model
- ✓ **Anti - steatotic effect** - Significant decrease in steatosis, ballooning and lobular inflammation (STAM)
- ✓ **ALT** - a decrease in plasma ALT and triglyceride levels (STAM & CCL4)
- ✓ **Liver protective effect** - Protects the liver against Ischemia/Reperfusion injury

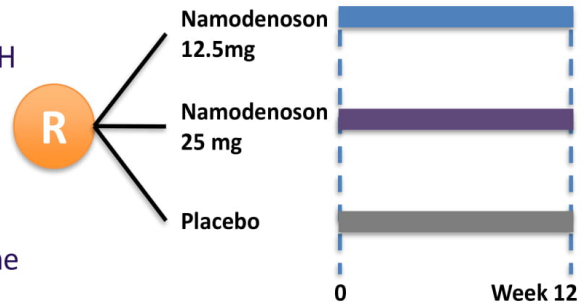
Robust Decrease in ALT



NASH – Phase II Study

Data expected to be released Q4 2019

- **Multicenter**, randomized, double-blinded, placebo-controlled, dose-finding efficacy and safety study
- 60 patients with NAFLD with or without NASH
- **Primary end point:** mean percent change from baseline in serum alanine aminotransferase (ALT) levels and safety
- **Secondary end point:** % change from baseline in hepatic steatosis measured by magnetic resonance imaging-determined proton-density fat-fraction (MRI-PDFF)



Leading KOLs (**Dr. Freidman**; Mount Sinai, **Dr. Arun Sanyal**; Virginia University, **Dr. Safadi**; Hadassah Jerusalem), on SAB and have advised on protocol design

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Spotlight on Milestones

- **Namodenoson:**

- NAFLD/NASH Phase II Data (~\$35B Opportunity) **Q4 2019**
- Liver Cancer Phase III Design & End of Phase II Meeting with FDA (~\$3.8B Opportunity) **H2 2019**

- **Piclidenoson:**

- Rheumatoid Arthritis Phase III (~\$35B Opportunity) **Ongoing**
- Psoriasis Phase III (~\$11.4B Opportunity) **Ongoing**

*Sources: Visiongain estimates global psoriasis drug market will be \$11.4b by 2020 and the global rheumatoid arthritis drug market will be \$34.6b by 2020; DelseInsight estimates the HCC drug market at \$3.8b in 2027; Grand View Research estimates the global erectile dysfunction drug market at \$3.2b by 2022; Deutsche Bank puts the peak market for NASH therapies at \$35b to \$40b by 2025.

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