
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 February 2025

001-36203
(Commission File Number)

CAN-FITE BIOPHARMA LTD.
(Exact name of Registrant as specified in its charter)

26 Ben Gurion Street
Ramat Gan 5257346 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 ☐

On February 5, 2025, Can-Fite BioPharma Ltd. (the “Company”) issued a press release entitled “Can-Fite BioPharma to Present the Namodenoson Anti-Obesity Effect at BIO CEO & Investor Conference 2025.” A copy of this press release is furnished herewith as Exhibit 99.1.

In addition, the Company has posted to its website an updated corporate presentation. A copy of the presentation is furnished herewith as Exhibit 99.2.

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated February 5, 2025
99.2	Corporate Presentation

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: February 5, 2025

By: /s/ Motti Farbstein
Motti Farbstein
Chief Executive Officer and Chief Financial Officer

Can-Fite BioPharma to Present the Namodenoson Anti-Obesity Effect at BIO CEO & Investor Conference 2025

Ramat Gan, Israel, Feb. 05, 2025 (GLOBE NEWSWIRE) -- Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE:CANF), a biotechnology company advancing a pipeline of proprietary small molecule drugs that address oncological and inflammatory diseases, today announced that it will present at the BIO CEO & Investor Conference, taking place February 10-11, 2025, in New York City.

Presentation Details:

- **Event:** BIO CEO & Investor Conference 2025
- **Date & Time:** February 10, 2025, at 3:45 pm EST
- **Location:** New York Marriott Marquis, New York City
- **Presenter:** Motti Farbstein, Chief Executive & Chief Financial Officer

During the conference, Can-Fite's management team will engage in one-on-one meetings with investors and potential partners to discuss the company's business strategy, recent clinical milestones, and upcoming development plans. To register for the conference and schedule a one-on-one meeting with Can-Fite management, please use the link [HERE](#).

Can-Fite's pipeline includes advanced-stage drug candidates targeting unmet medical needs in oncology, metabolic diseases, and inflammatory conditions. The company's lead drug candidate, *Namodenoson*, is in a pivotal Phase III trial for advanced liver cancer and a Phase IIb study for Metabolic Dysfunction-associated Steatohepatitis (MASH). Additionally, *Piclidenoson* is preparing to advance into a pivotal Phase III trial for psoriasis.

About Can-Fite BioPharma Ltd.

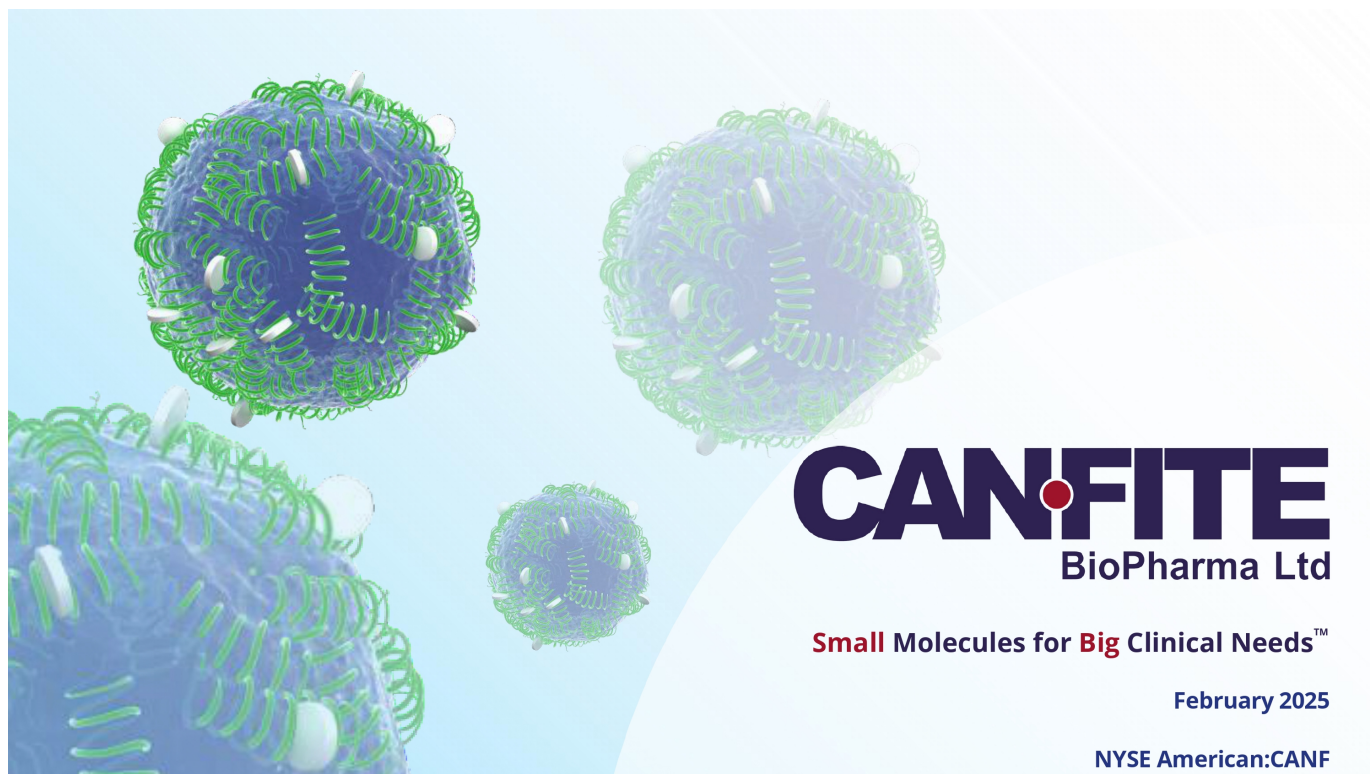
Can-Fite BioPharma Ltd. (NYSE American: CANF) (TASE: CANF) is an advanced clinical stage drug development Company with a platform technology that is designed to address multi-billion-dollar markets in the treatment of cancer, liver, and inflammatory disease. The Company's lead drug candidate, Piclidenoson recently reported topline results in a Phase III trial for psoriasis and is expected to commence a pivotal Phase III. Can-Fite's liver drug, Namodenoson, is being evaluated in a Phase III trial for hepatocellular carcinoma (HCC), a Phase IIb trial for the treatment of MASH, and in a Phase IIa study in pancreatic cancer. Namodenoson has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second line treatment for HCC by the U.S. Food and Drug Administration. Namodenoson has also shown proof of concept to potentially treat other cancers including colon, prostate, and melanoma. CF602, the Company's third drug candidate, has shown efficacy in the treatment of erectile dysfunction. These drugs have an excellent safety profile with experience in over 1,600 patients in clinical studies to date. For more information please visit: <https://www.canfite.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. 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; 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; risks related to any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; risks related to not satisfying the continued listing requirements of NYSE American; 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, 2024 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.

Contact

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CANFITE
BioPharma Ltd

Small Molecules for Big Clinical Needs™

February 2025

NYSE American:CANF

Forward Looking Statement

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Company Overview

NYSE American: CANF

1

**Safe Drugs for the Treatment of
Oncological and Inflammatory Diseases**

2

**Advanced Clinical Stage Pipeline;
Short Regulatory Approval Pathway
(FDA & EMA)**

3

Successful Out-licensing Deals

4

Financial Summary

(Ticker: CANF) Listed on NYSE American and Tel-Aviv Stock Exchange
~10M ADRs outstanding; ~3,000M ordinary shares outstanding
(1 ADR = 300 Ordinary Shares)
Cash: ~\$8M as of December 31, 2024*

*Cash balance is unaudited

Unique Platform Technology

Specific oral therapy aimed at diseased cells

Therapeutic Target

- Global leader in discovering and developing drugs that target the A3 adenosine receptor (A3AR)

Pipeline Drugs

- Small molecule, orally bioavailable drugs
- Bind only to pathological cells, not normal cells

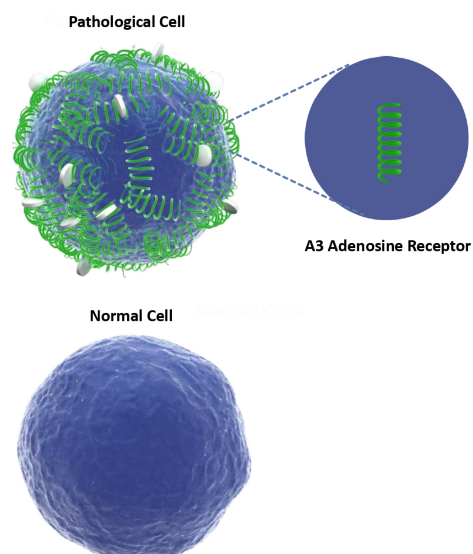
Proven Therapeutic Effect

- Good efficacy and safety with anti-inflammatory and anti-cancer effects shown in Phase 2 and Phase 3 studies

Excellent Safety Profile

- Demonstrated in >1600 patients







NYSE American: CANF



Pipeline Drugs

Drug/Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
Piclidenoson				
Psoriasis	Pivotal Phase III agreed with FDA & EMA			
Lowe syndrome	Phase II to be initiated			
Dogs Osteoarthritis	Positive Phase II data; Out licensed to Vetbiolix			
Namodenoson				
Liver Cancer	Pivotal Phase III agreed with FDA & EMA; Ongoing			
Pancreatic Cancer	Phase IIa Ongoing			
MASH	Phase IIb Ongoing			
CF602				
Erectile Dysfunction	Ongoing			

Corporate Partnerships: Current Out-Licensing Deals

	Eastern Europe	<i>Psoriasis, Liver Cancer, MASH Pancreatic cancer</i>
 Gebro Pharma	Spain, Switzerland, Austria	<i>Psoriasis</i>
	China, Taiwan, Hong Kong, Macao	<i>Psoriasis, Liver Cancer, MASH</i>
	South Korea	<i>Liver Cancer, MASH</i>
	South Korea	<i>Psoriasis</i>
	Canada	<i>Psoriasis</i>
VETBIOLIX	Global	<i>Piclidenoson - Pets' Osteoarthritis</i>

\$20M

received in upfront and milestone payments

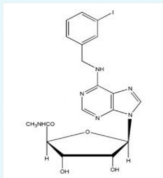
\$130M

potential based on regulatory and sales milestones

Typical Deal Structure

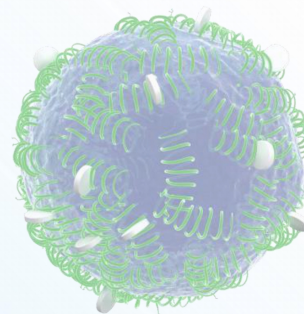
- Up-front money upon signing a distribution deal
- Regulatory milestone payments
- **Royalties (double-digits)**
- Sales milestone payments

Piclidenoson Drug Candidate



Chemical Properties

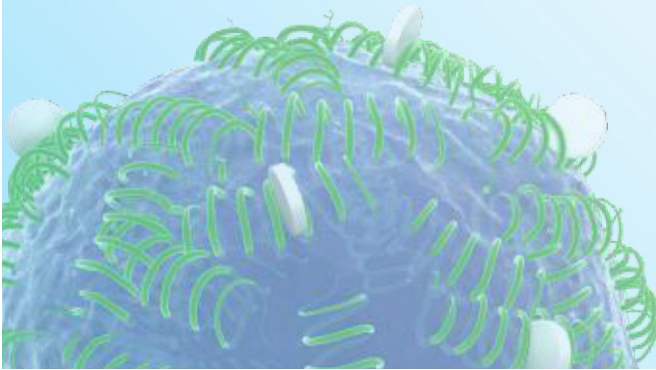
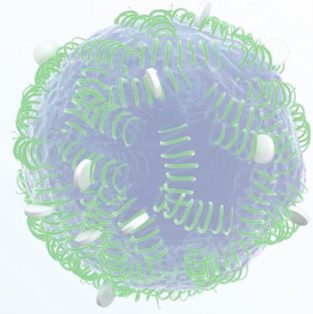
- Nucleoside derivative
- Highly Selective A3AR Agonist
- Molecular weight - 510.29
- Water insoluble
- Half lifetime in blood – 8-9 hours



Piclidenoson
Inflammatory Indications

Piclidenoson

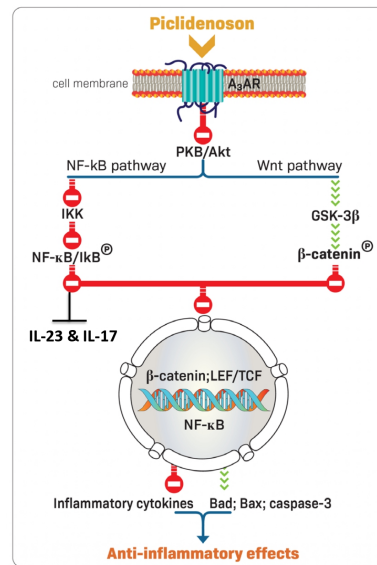
Moderate to Severe Psoriasis



Piclidenoson for the Treatment of Plaque Psoriasis

Rational for Development

- Overexpression of the A3AR target in Keratinocytes of psoriasis patients
- Robust anti-inflammatory effect manifested by specific apoptosis of inflammatory cells
- Piclidenoson inhibits **IL-17 & IL-23** production in keratinocytes
- Piclidenoson had significant anti-psoriatic effects and promising safety profile in a Phase 3 trial in patients with moderate-to-severe plaque psoriasis.

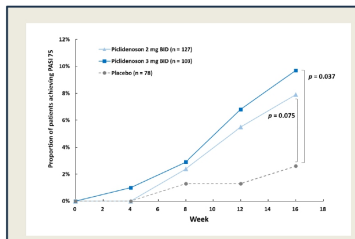


Phase III Study Endpoints - Achieved

Comfort |

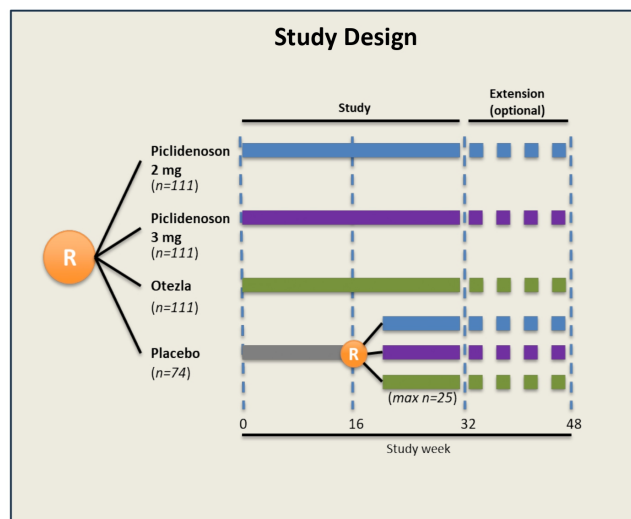
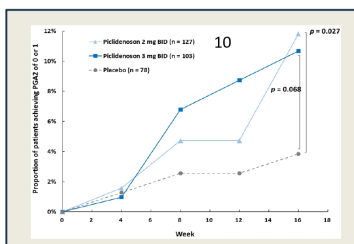
Primary Endpoint

PASI 75 Significant Superiority of
Piclidenoson 3 mg vs. Placebo



Secondary Endpoint

Subjects Achieving PGA2 for
Piclidenoson vs Placebo



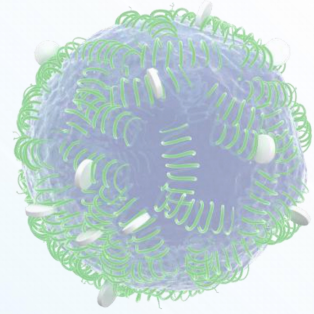
NYSE American: CANF

Excellent Safety Profile

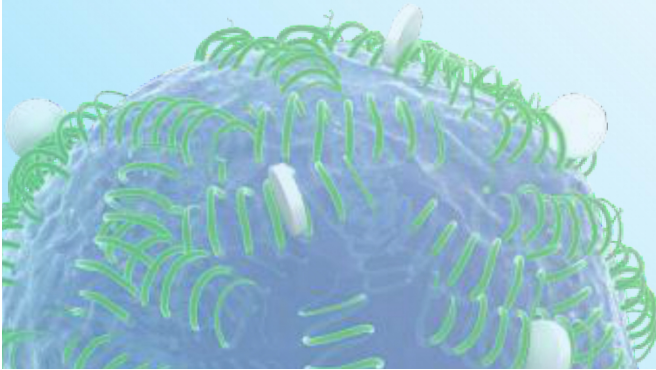
- Pivotal Phase III study that has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- Oral piclidenoson 3 mg twice daily (BID) in subjects with moderate-to-severe plaque psoriasis, compared with placebo
- The co-primary Primary Objectives of this study:
 - Proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response at Week 16 of $\geq 75\%$ (PASI 75); and
 - Proportion of subjects who achieve a Static Physician's Global Assessment (sPGA) at Week 16 of 0 or 1 with at least a 2-point improvement from Baseline.
- The primary safety objective of this - Evaluate the safety of oral piclidenoson in this population.

Piclidenoson

Osteoarthritis in Pets



**Partnership with
Veterinarian Company
Vetbiolix**



Osteoarthritis in Pets

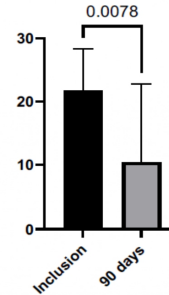
- The canine osteoarthritis market is projected to reach \$3 billion by 2028
- Vetbiolix exercised the option to enter into a full in license agreement with Can-Fite
- Projected Income of \$325M¹ to Can-Fite Over the Next 10 Years After Vetbiolix Exercised its Option

Rational for Development

- A3AR is over-expressed in inflamed synovial cells
- Piclidenoson has robust anti-inflammatory effect manifested by inhibition of osteoarthritis in murine models
- Clinical study in beagles has been successfully concluded reaching primary and secondary endpoints
- Primary objective was LOAD (Liverpool Osteoarthritis in Dogs)

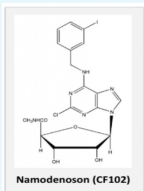
Inhibition of Osteoarthritis in Dogs

LOAD before and after treatment in 500 µg/kg group
(Primary Endpoint; geometric mean \pm 95% CI)



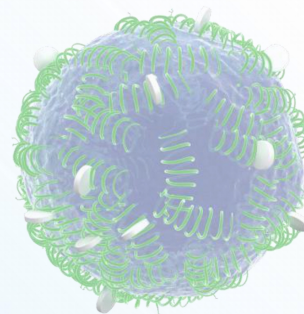
¹The arthritis market for companion animals is estimated by [Coherent Market Insights](#) to be \$3.8 Billion in 2023 and is expected to grow to \$6.3 Billion by 2030. Can-Fite and Vetbiolix model that Piclidenoson has the potential to capture up to 6% of this opportunity, with peak worldwide sales of \$445 Million by 2034. Under the agreement, Can-Fite is entitled to receive a 15% royalty on worldwide sales in this indication. This means that Can-Fite's upfront and royalties on sales upon regulatory approval for veterinary use, is projected to be \$325 million in the aggregate over the next decade assuming a 2027 launch.

Namodenoson Drug Candidate



Chemical Properties

- MW: 544.73 g/mol
- Water Insoluble
- Half life: 12 hours
- Nucleoside Derivative
- Orally Bioavailable
- High Stability in the Liver



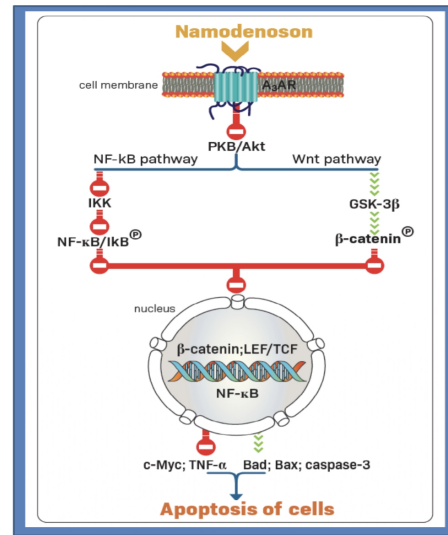
Namodenoson

Oncology & MASH (NASH)

Advanced Liver Cancer

Rational for Development

- A3AR is over-expressed in human hepatocellular carcinoma (HCC) cells.
- Namodenoson, induces de-regulation of the Wnt and NF- κ B signalling pathways resulting in apoptosis of HCC cells.
- In Phase II study in patients with advanced HCC, Namodenoson was safe and well tolerated. Evidence of antitumor activity was observed.



HCC Phase II Study – Recent Data

Presented at the AASLD 2022 & ASCO-Breakthrough 2023 Meeting

Complete Response in a Namodenoson Treated Patient

- Patient was enrolled in Phase II liver cancer study
- Continued treatment with Namodenoson for >7 years under Open Label Extension Program in Europe¹⁶
- Patient had Complete Response: Completely cleared all cancer lesions
- Over the course of 7 years, clinical benefits included:
 - Disappearance of ascites
 - Return to normal liver function
 - Disappearance of peritoneal carcinomatosis

Complete disappearance
of tumor lesions



Liver Cancer

Pivotal Phase III Ongoing

*Orphan Drug Designation
with FDA&EMA*

*Fast Track Designation with
FDA*

Interim Analysis

NYSE American: CANF

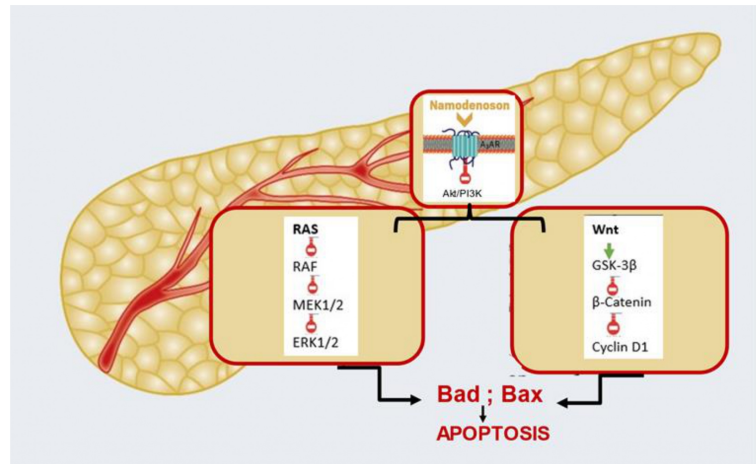


- **FDA and EMA** agreed on Pivotal Phase 3 study protocol
- **Interim analysis** to be conducted by Independent Data Monitoring Committee (IDMC) after 50% of planned 450 patients are enrolled and treated
- **Namodenoson evaluated as a 2nd- or 3rd-line** treatment for advanced liver cancer patients in whom other approved therapies have not been or are no longer effective
- **Primary endpoint** - overall survival
- **Orphan Drug Status** - granted by FDA and EMA
- **Fast Track Status** - granted by FDA
- **Compassionate Use Program** - currently treating liver cancer patients in Israel and Romania

Pancreatic Cancer

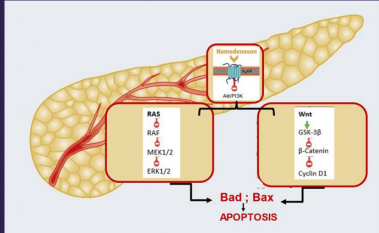
Rationale for Development

- Namodenoson induces 90% growth inhibition of pancreatic cancer cells
- The molecular mechanism of action includes de-regulation of the Wnt and the Ras signaling pathways
- *In vivo* studies showed robust inhibition of pancreatic tumor size



Pancreatic Cancer

Currently Enrolling Patients for a Phase IIa Study



NYSE American: CANF

Exploratory Phase IIa Study

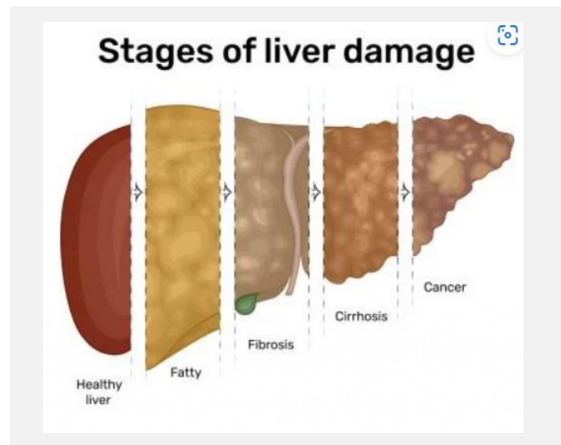
Second line therapy

- **Open label**
- **Oral dose of Namodenoson:** 25 mg twice daily
- **Primary End point:** Safety
- **Secondary Endpoints:** Objective response, progression-free survival, duration of response, disease control (defined as an objective response or stable disease), overall survival

MASH - Metabolic Associated Steatohepatitis

Rational for Development: Liver protective Effect

- Induction of anti-inflammatory effect manifested by reduction of NAFLD Activity Score (NAS)
- Anti-fibrotic effect
- Anti-steatotic effect: significant decrease in steatosis, ballooning and lobular inflammation
- Decrease in ALT, AST, Triglyceride levels
- Namodenoson protects the liver against Ischemia/Reperfusion injury



MASH (NASH)

Addressing Severe Unmet Need

*Currently Enrolling Patients for
a Phase IIb Study*

*US Patent Office Granted
Can-Fite Namodenoson Patent
for Use as anti-Obesity Drug*

NYSE American: CANF

Phase IIa Study Successfully Concluded:

- Reduced liver fat content (LFC)
- Anti-Inflammatory effect
- Dose selection for Phase IIb determined
- **Decrease in body weight**
- Excellent safety profile

Phase IIb Study

- Multicenter, randomized, double-blind, placebo-controlled study in 130 subjects with biopsy-confirmed MASH
- Subjects are randomly assigned in a 2:1 ratio to oral doses of Namodenoson 25 mg every 12 hours or a matching placebo for 36 weeks
- Regular evaluation for safety and efficacy biomarkers baseline measurements at weeks 6, 12, 24, and 36
- Primary efficacy endpoint will be determined by liver biopsy at week 36

CF602

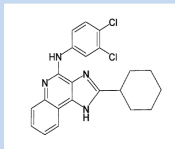
Erectile Dysfunction (ED)

Rationale:

Anecdotal reports from patients treated with Can-Fite drugs, both women and men, testifying that the drugs reversed their sexual dysfunction

NYSE American: CANF

Chemical Formula:



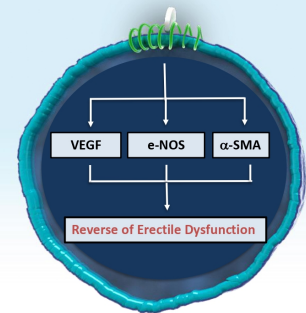
Properties:

- A3AR allosteric modulator
- Molecular weight – 411.34
- Water insoluble
- Orally bioavailable

Activity:

- Significant full recovery from erectile dysfunction in a diabetic rat model
- Topically & Systemic
- Dose-dependent, linear effect
- Response after single dose of CF602

Mechanism of Action



- Up-regulation of eNOS and VEGF
- Improves vasodilation and smooth muscle relaxation

Closing Highlights

1

Oral drugs with proven safety and efficacy in Pivotal Phase III studies

Piclidenoson and Namodenoson are Phase III assets in psoriasis and liver cancer; Namodenoson showed strong efficacy in a Phase II SLD study and is headed into an exploratory Phase IIa study in pancreatic cancer

2

Monetizing advanced portfolio through corporate partnerships –

Piclidenoson and Namodenoson have been out-licensed in select territories with ~\$20 million received to date and potentially up an additional \$130 million plus royalties

3

Novel therapeutic approach – Unique technology for the treatment of cancer, liver and inflammatory diseases; addressing multi-billion dollar markets

4

Intellectual property portfolio – Consists of 15 patent families issued and pending to protect the different indications

5

Financially well positioned – To conduct all clinical development programs and G&A for > 1 year