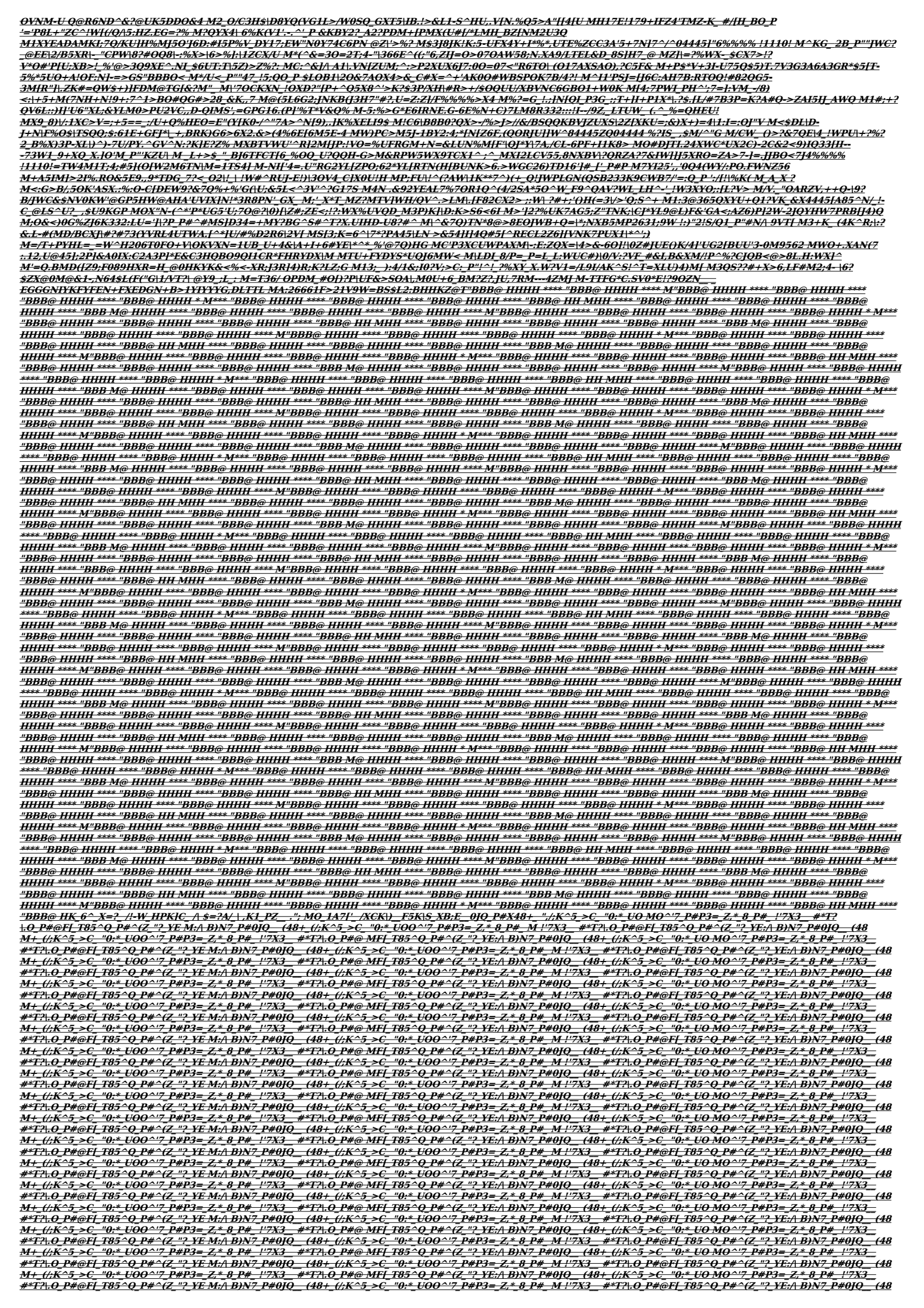

0001213900-25-0102486-K Can-Fite BioPharma Ltd. 2025020520250205070236070238070238 0 0001213900-25-010248 6-K 26 20250205 20250205 20250205 Can-Fite BioPharma Ltd. 0001536196 2834 000000000 L3 1231 6-K 34 001-36203 25590849 26 BEN GURION STREET RAMAT GAN L3 5257346 972 39241114 26 BEN GURION STREET RAMAT GAN L3 5257346 6-K 1 ea0230008-6k_canfite.htm REPORT OF FOREIGN PRIVATE ISSUER Â Â UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 Â FORM 6-K Â Report of Foreign Private Issuer Pursuant to RuleÂ 13a-16 or 15d-16 Under the Securities Exchange Act of 1934 Â For the Month of February 2025 Â 001-36203 (Commission File Number) Â CAN-FITE BIOPHARMA LTD. (Exact name of Registrant as specified in its charter) Â 26 Ben Gurion Street Ramat Gan 5257346 Israel (Address of principal executive offices) Â Indicate by check mark whether the registrant files or will file annual reports under cover FormÂ 20-F or FormÂ 40-F. Â FormÂ 20-FÂ â˜’Â Â Â Â Â Â Â Â Â Â Â FormÂ 40-FÂ â˜ Â Â Â Â Â Â On February 5, 2025, Can-Fite BioPharma Ltd. (the â€œCompanyâ€) issued a press release entitled â€œCan-Fite BioPharma to Present the Namodenoson Anti-Obesity Effect at BIO CEO & Investor Conference 2025.â€ A copy of this press release is furnished herewith as Exhibit 99.1. Â 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. Â 1 Â Â Exhibit Index Â Exhibit No. Â Description 99.1 Â Press Release dated February 5, 2025 99.2 Â Corporate Presentation Â 2 Â Â SIGNATURES Â 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. Â Date: February 5, 2025 By: /s/ Motti Farbstein Â Â Motti Farbstein Â Â Chief Executive Officer and Chief Financial Officer Â Â 3 Â EX-99.1 2 ea023000801ex99-1_canfite.htm PRESS RELEASE DATED FEBRUARY 5, 2025 Exhibit 99.1 Â Can-Fite BioPharma to Present the Namodenoson Anti-Obesity Effect at BIO CEO & Investor Conference 2025 Â 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. Â Presentation Details: Â â—Event: BIO CEO & Investor Conference 2025 Â â—Date & Time: February 10, 2025, at 3:45 pm EST Â â—Location: New York Marriott Marquis, New York City Â â—Presenter: Motti Farbstein, Chief Executive & Chief Financial Officer Â During the conference, Can-Fiteâ€™s management team will engage in one-on-one meetings with investors and potential partners to discuss the companyâ€™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 linkÂ HERE. Â Can-Fiteâ€™s pipeline includes advanced-stage drug candidates targeting unmet medical needs in oncology, metabolic diseases, and inflammatory conditions. The companyâ€™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. Â About Can-Fite BioPharma Ltd. Â 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 Companyâ€™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-Fiteâ€™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 Companyâ€™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/. Â Â Â Â Forward-Looking Statements Â This press release may contain forward-looking statements, about Can-Fiteâ€™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 â€œforward looking statementsâ€. Forward-looking statements can be identified by the use of forward-looking words such as â€œbelieve,â€ â€œexpect,â€ â€œintend,â€ â€œplan,â€ â€œmay,â€ â€œshouldâ€ or â€œanticipateâ€ 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-Fiteâ€™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 â€œRisk Factorsâ€ section of Can-Fiteâ€™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. Â Contact Â Can-Fite BioPharma Motti Farbstein info@canfite.com +972-3-9241114 Â Â Â Â Â EX-99.2 3 ea023000801ex99-2_canfite.htm CORPORATE PRESENTATION Exhibit 99.2 Â Small Molecules for Big Clinical Needs TM NYSE American:CANF February 2025 Â Â Forward Looking Statement This presentation may contain forward - looking statements, about Can - Fiteâ€™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 â€œforward looking statementsâ€ . Forward - looking statements can be identified by the use of forward - looking words such as â€œbelieve,â€ â€œexpect,â€ â€œintend,â€ â€œplan,â€ â€œmay,â€ â€œshouldâ€ or â€œanticipateâ€ 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 - Fiteâ€™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 â€œRisk Factorsâ€ section of Can - Fiteâ€™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 . NYSE American: CANF Â Â Safe Drugs for the Treatment of Oncological and Inflammatory Diseases Advanced Clinical Stage Pipeline; Short Regulatory Approval Pathway (FDA & EMA) Successful Out - licensing Deals Company Overview 1 2 3 Financial Summary 4 NYSE American: CANF Â Â Global leader in discovering and developing drugs that target the A3 adenosine receptor (A3AR) Therapeutic Target â€¢ Demonstrated in > 1600 patients Excellent Safety Profile â€¢ Good efficacy and safety with anti - inflammatory and anti - cancer effects shown in Phase 2 and Phase 3 studies Proven Therapeutic Effect â€¢ Small molecule, orally bioavailable drugs â€¢ Bind only to pathological cells, not normal cells Pipeline Drugs Unique Platform Technology Specific oral therapy aimed at diseased cells A3 Adenosine Receptor Pathological Cell Normal Cell NYSE American: CANF Â Â Pipeline Drugs Piclidenoson Phase 1 Phase 3 Phase 2 Pre - Clinical Namodenoson Psoriasis Pivotal Phase III agreed with FDA & EMA MASH Phase IIb Ongoing CF602 Erectile Dysfunction Ongoing Drug/Indication Pancreatic Cancer Phase IIa Ongoing Liver Cancer Pivotal Phase III agreed with FDA & EMA; Ongoing Lowe syndrome Phase II to be initiated Dogs Osteoarthritis Positive Phase II data; Out licensed to Vetbiolix NYSE American: CANF Â Â potential based on regulatory and sales milestones $ 20M received in upfront and milestone payments $ 130 M Psoriasis, Liver Cancer, MASH Liver Cancer, MASH Psoriasis Psoriasis Psoriasis, Liver Cancer, MASH Pancreatic cancer Typical Deal Structure â€¢ Up - front money upon signing a distribution deal â€¢ Regulatory milestone payments â€¢ Royalties (double - digits) â€¢ Sales milestone payments VETBIOLIX Psoriasis Piclidenoson - Pets â€™ Osteoarthritis Canada Spain, Switzerland, Austria South Korea South Korea China, Taiwan, Hong Kong, Macao Global Eastern Europe Corporate Partnerships: Current Out - Licensing Deals Â Â Inflammatory Indications Piclidenoson â€¢ Nucleoside derivative â€¢ Highly Selective A 3 AR Agonist â€¢ Molecular weight - 510.29 â€¢ Water insoluble â€¢ Half lifetime in blood â€“ 8 - 9 hours Piclidenoson Drug Candidate Chemical Properties Â Â Moderate to Severe Psoriasis Piclidenoson Â Â â€¢ Overexpression of the A3AR target in Keratinocytes of psoriasis patients â€¢ Robust anti - inflammatory effect manifested by specific apoptosis of inflammatory cells â€¢ Piclidenoson inhibits IL - 17 & IL - 23 production in keratinocytes â€¢ Piclidenoson had significant anti - psoriatic effects and promising safety profile in a Phase 3 trial in patients with moderate - to - severe plaque psoriasis. Piclidenoson for the Treatment of Plaque Psoriasis IL - 23 & IL - 17 Rational for Development Â Â Phase III Study Endpoints - Achieved PASI 75 Significant Superiority of Piclidenoson 3 mg vs. Placebo Primary Endpoint Secondary Endpoint Subjects Achieving PGA 2 for Piclidenoson vs Placebo I Study Design Excellent Safety Profile 10 NYSE American: CANF Â Â Pivotal Phase III II â€¢ Pivotal Phase III study that has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). â€¢ Oral piclidenoson 3 mg twice daily (BID) in subjects with moderate - to - severe plaque psoriasis, compared with placebo â€¢ The co - primary Primary Objectives of this study: â€¢ Proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response at Week 16 of â‰¥ 75 % (PASI 75); and â€¢ 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. â€¢ The primary safety objective of this - Evaluate the safety of oral piclidenoson in this population. 11 NYSE American: CANF Â Â Osteoarthritis in Pets Piclidenoson Partnership with Veterinarian Company Vetbiolix Â Â A 3 AR is over - expressed in inflamed synovial cells â€¢ Piclidenoson has robust anti - inflammatory effect manifested by inhibition of osteoarthritis in murine models â€¢ Clinical study in beagles has been successfully concluded reaching primary and secondary endpoints â€¢ Primary objective was LOAD (Liverpool Osteoarthritis in Dogs) Rational for Development Inhibition of Osteoarthritis in Dogs Osteoarthritis in Pets â€¢ The canine osteoarthritis market is projected to reach $ 3 billion by 2028 â€¢ Vetbiolix exercised the option to enter into a full in license agreement with Can - Fite â€¢ Projected Income of $ 325 M 1 to Can - Fite Over the Next 10 Years After Vetbiolix Exercised its Option 1 The 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 â€™ 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. Â Â Oncology & MASH (NASH) Namodenoson â€¢ MW: 544.73 g/mol â€¢ Water Insoluble â€¢ Half life: 12 hours â€¢ Nucleoside Derivative â€¢ Orally Bioavailable â€¢ High Stability in the Liver Namodenoson Drug Candidate Chemical Properties Â Â A 3 AR is over - expressed in human hepatocellular carcinoma (HCC) cells. â€¢ Namodenoson, induces de - regulation of the Wnt and NF - kB signalling pathways resulting in apoptosis of HCC cells. â€¢ In Phase II study in patients with advanced HCC, Namodenoson was safe and well tolerated. Evidence of antitumor activity was observed. Rational for Development IL - 23 & IL - 17 Advanced Liver Cancer Â Â HCC Phase II Study â€“ Recent Data â€¢ Patient was enrolled in Phase II liver cancer study â€¢ Continued treatment with Namodenoson for > 7 years under Open Label Extension Program in Europe â€¢ Patient had Complete Response: Completely cleared all cancer lesions â€¢ Over the course of 7 years, clinical benefits included: Â» Disappearance of ascites Â» Return to normal liver function Â» Disappearance of peritoneal carcinomatosis Complete disappearance of tumor lesions Presented at the AASLD 2022 & ASCO - Breakthrough 2023 Meeting Complete Response in a Namodenoson Treated Patient 16 Â Â FDA and EMA agreed on Pivotal Phase 3 study protocol â€¢ Interim analysis to be conducted by Independent Data Monitoring Committee (IDMC) after 50 % of planned 450 patients are enrolled and treated â€¢ Namodenoson evaluated as a 2 nd - or 3 rd - line treatment for advanced liver cancer patients in whom other approved therapies have not been or are no longer effective â€¢ Primary endpoint - overall survival â€¢ Orphan Drug Status - granted by FDA and EMA â€¢ Fast Track Status - granted by FDA â€¢ Compassionate Use Program - currently treating liver cancer patients in Israel and Romania Orphan Drug Designation with FDA&EMA Fast Track Designation with FDA Interim Analysis Liver Cancer Pivotal Phase III Ongoing Â Â Namodenoson induces 90 % growth inhibition of pancreatic cancer cells â€¢ The molecular mechanism of action includes de - regulation of the Wnt and the Ras signaling pathways â€¢ In vivo studies showed robust inhibition of pancreatic tumor size Rationale for Development Pancreatic Cancer NYSE American: CANF Â Â Pancreatic Cancer Second line therapy â€¢ Open label â€¢ Oral dose of Namodenoson: 25 mg twice daily â€¢ Primary End point: Safety â€¢ Secondary Endpoints: Objective response, progression - free survival, duration of response, disease control (defined as an objective response or stable disease), overall survival Exploratory Phase IIa Study Currently Enrolling Patients for a Phase IIa Study Â Â Induction of anti - inflammatory effect manifested by reduction of NAFLD Activity Score (NAS) â€¢ Anti - fibrotic effect â€¢ Anti - steatotic effect: significant decrease in steatosis, ballooning and lobular inflammation â€¢ Decrease in ALT, AST, Triglyceride levels â€¢ Namodenoson protects the liver against Ischemia/Reperfusion injury Rational for Development: Liver protective Effect MASH - Metabolic A ssociated Steatohepatitis Â Â Phase IIa Study Successfully Concluded: â€¢ Reduced liver fat content (LFC) â€¢ Anti - Inflammatory effect â€¢ Dose selection for Phase IIb determined â€¢ Decrease in body weight â€¢ Excellent safety profile 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 Phase IIb Study â€¢ Multicenter, randomized, double - blind, placebo - controlled study in 130 subjects with biopsy - confirmed MASH â€¢ 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 â€¢ Regular evaluation for safety and efficacy biomarkers baseline measurements at weeks 6 , 12 , 24 , and 36 â€¢ Primary efficacy endpoint will be determined by liver biopsy at week 36 MASH (NASH) Â Â VEGF - SMA e - NOS Reverse of Erectile Dysfunction Mechanism of Action Up - regulation of eNOS and VEGF â€¢ Improves vasodilation and smooth muscle relaxation Rationale: Anecdotal reports from patients treated with Can - Fite drugs, both women and men, testifying that the drugs reversed their sexual dysfunction Properties: â€¢ A 3 AR allosteric modulator â€¢ Molecular weight â€“ 411.34 â€¢ Water insoluble â€¢ Orally bioavailable Activity: â€¢ Significant full recovery from erectile dysfunction in a diabetic rat model â€¢ Topically & Systemic â€¢ Dose - dependent, linear effect â€¢ Response after single dose of CF 602 CF 602 Erectile Dysfunction (ED) Chemical Formula: 22 Â Â Monetizing advanced portfolio through corporate partnerships â€“ 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 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 Novel therapeutic approach â€“ Unique technology for the treatment of cancer, liver and inflammatory diseases; addressing multi - billion dollar markets Intellectual property portfolio â€“ Consists of 15 patent families issued and pending to protect the different indications Financially well positioned â€“ To conduct all clinical development programs and G&A for > 1 year Closing Highlights NYSE American: CANF Â GRAPHIC 4 ex99-2_001.jpg GRAPHIC begin 644 ex99-2_001.jpg

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