

Can-Fite Presentation 公司报告

May 2021 / 2021年5月

Forward Looking Statement 前瞻性陈述

- 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; impact of the recent outbreak of the COVID-19 pandemic; 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 25, 2021 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.

Company Profile 公司介绍

- **Advanced clinical stage drug** development company with small molecule drug products for the treatment of inflammatory and cancer indications 高级临床阶段药物开发公司，拥有治疗炎症和癌症适应症的小分子药物产品
- **Robust clinical proof of concept** from Phase II and Phase III clinical studies; Technology is covered by 15 Patent Families 二期和三期临床研究的强大的临床概念证明；技术被15个专利家族所覆盖
- **Successful out-licensing deals** with ~\$20 M received to date and an additional ~\$130 M in potential milestone payments plus double-digit royalties on net sales following regulatory approval 成功的授权交易，迄今已收到约\$2,000万，另外还有约\$1.3亿的潜在里程碑付款，以及监管部门批准后净销售额的两位数权利金。
- **Listed on NYSE American (CANF) and Tel-Aviv Stock Exchange (CFBI);**
~17.2 M ADRs outstanding; ~516 M ordinary shares outstanding
(*1 ADR = 30 Ordinary Shares) 在纽约美国证券交易所（**CANF**）和特拉维夫证券交易所（**CFB**）上市。已发行的美国存托凭证约1720万份；已发行的普通股约5.16亿股（*1 ADR = 30股普通股）

Unique Platform Technology 独特的平台技术

Specific therapy aimed at diseased cells 针对病变细胞的特定疗法

Therapeutic Target 治疗靶点

- A₃ adenosine receptor / A₃腺苷受体 (A₃AR)
- Highly expressed in pathological cells 在病理细胞中高表达

Drug product 药物产品

- Small molecule 小分子
- Orally bioavailable drug 口服生物药物

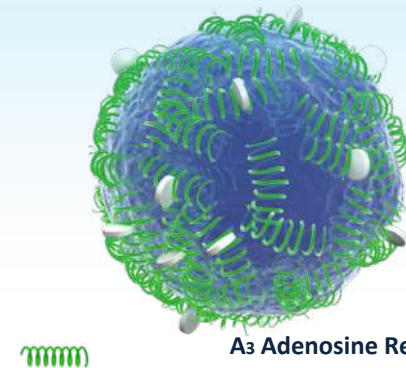
Proven Therapeutic Effect 经过验证的治疗效果

- Anti-inflammatory and anti-cancer effects shown in Phase II studies; 二期研究显示有抗炎和抗癌作用。

Excellent Safety Profile 出色的安全性能

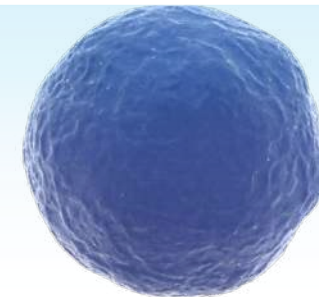
Demonstrated in >1500 patients 在超过1500名患者中得到证明

Pathological Cells 病理细胞



A₃ Adenosine Receptor
/ A₃腺苷受体 (A₃AR)

Normal Cells 正常细胞



Drug Development Pipeline 药物开发管线

Drug 药物	Pre-clinical 临床前	Phase I 一期	Phase II 二期	Phase III 三期	Market 市场
Piclidenoson					~\$11.3B 约113亿
• Psoriasis 银屑病		Enrollment Ongoing 招募正在进行			
• COVID-19 新冠病毒		Enrollment Ongoing 招募正在进行			~\$10B 约100亿
Namodenoson					~\$3.8B 约38亿
• Liver Cancer 肝癌		Under Preparation 正在筹备			
• NASH		Under Preparation 正在筹备			~\$35B 约350亿
CF602					~\$3.2B 约32亿
• ED		Ongoing 正在进行			
Cannabinoids					~\$56.7B 约567亿
		Ongoing 正在进行			

*Sources: iHealthAnalyst estimated the global psoriasis drug market will be \$11.3 B by the end of 2025; Morningstar projects sales of pharmaceuticals to treat COVID-19 will reach \$10 B in 2021; DelveInsight estimates the HCC drug market at \$3.8B in 2027; Deutsche Bank puts the peak market for NASH therapies at \$35B to \$40B by 2025; Grand View Research estimates the global erectile dysfunction drug market at \$3.2B by 2022; Adroit Market Research estimates that the medical cannabis market is projected to grow at CAGR of 29% to \$56.7B by 2026 *来源: iHealthAnalyst 估计, 到2025年底, 全球银屑病药物市场将达到\$113亿; Morningstar 预计, 2021年治疗新冠病毒的药品销售额将达到\$100亿; DelveInsight 估计, HCC 药物市场在\$38亿; 德意志银行认为, 到2025年, NASH 疗法的峰值市场为\$350亿至\$400亿; Grand View Research 估计, 到2022年, 全球勃起功能障碍药物市场为\$32亿; Adroit Market Research 估计, 到2026年, 医用大麻市场预计将以29%的年复合增长率增长到\$567亿。

(NYSE American: CANF) (TASE:CFBI)

Robust Clinical Proof of Concept 强有力的临床概念证明

Psoriasis Phase III 银屑病三期

- Positive recommendation to continue patient enrollment has been received from a committee that looked at the data from 50% of patients that were enrolled
一个委员会已经给出继续招募患者的积极建议，该委员会研究了50%被招募的患者的数据。

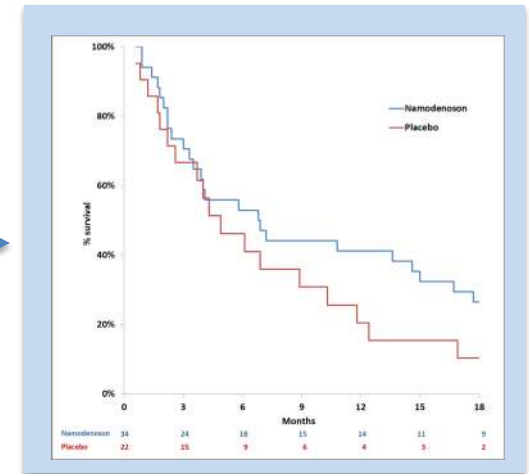
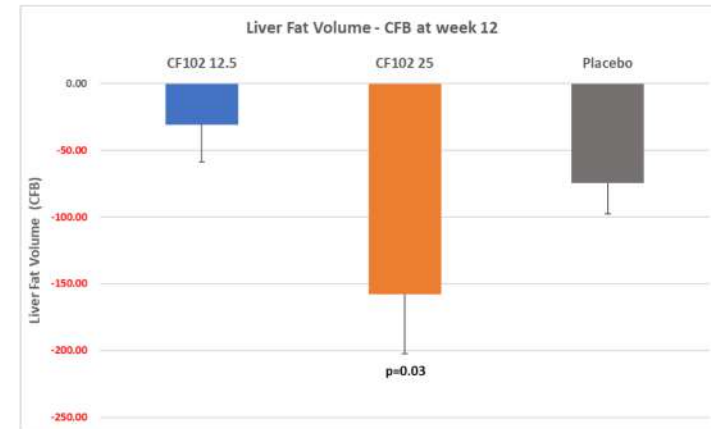
NASH Phase IIa / NASH IIa期

- Significant anti-steatotic, anti-fibrotic and anti-inflammatory effects 显著的抗脂肪血症、抗纤维化和抗炎作用

Advanced Liver Cancer 晚期肝癌

- Overall survival superiority in Child Pugh B7 patients treated with Namodenoson 用Namodenoson治疗的Child Pugh B7患者的总生存率优势

MRI PDFF – Liver Fat Volume CFB at week 12
第12周时的肝脂肪量CFB



Typical Deal Structure 典型的交易结构:

- Up-front money upon signing a distribution deal 签署分销协议后首付款
- Regulatory milestone payments 监管机构批准里程碑付款
- Royalties (double-digit) 权利金（两位数）
- Sales milestone payments 销售里程碑付款



Gebro Pharma



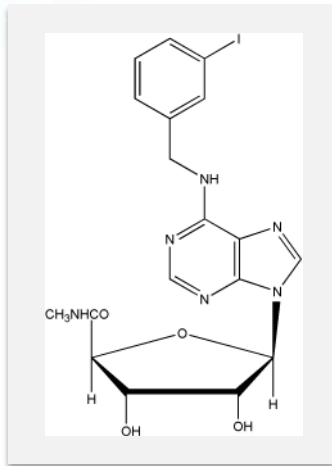
Chong Kun Dang
Pharm.
Seoul, Korea



\$20 million received in upfront and milestone payments 已收到首付款和里程碑付款\$2000万
\$130 million more potential based on regulatory and sales milestones 基于监管批准和销售里程碑，有望再获得\$1.3亿付款

(NYSE American: CANF) (TASE:CFBI)

Piclidenoson – Anti-Inflammatory Drug 抗炎症药物



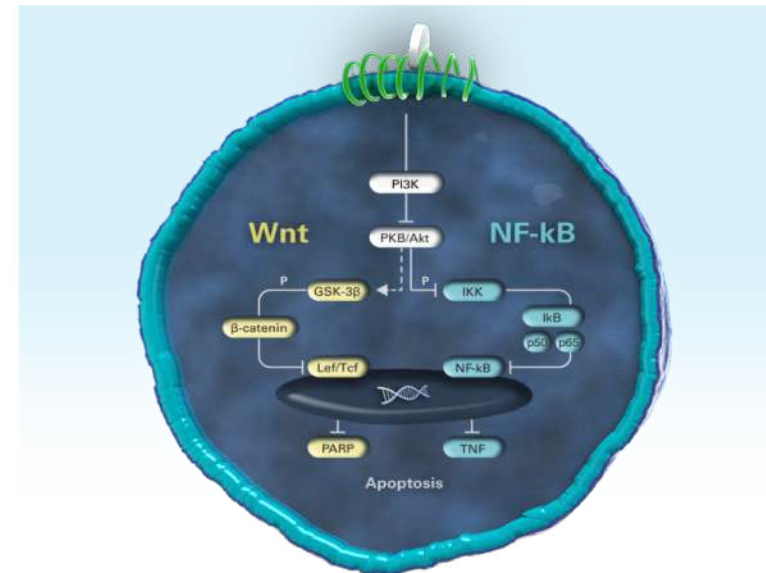
Chemical Formula
化学式

Piclidenoson

Psoriasis & COVID-19

银屑病和新冠病毒

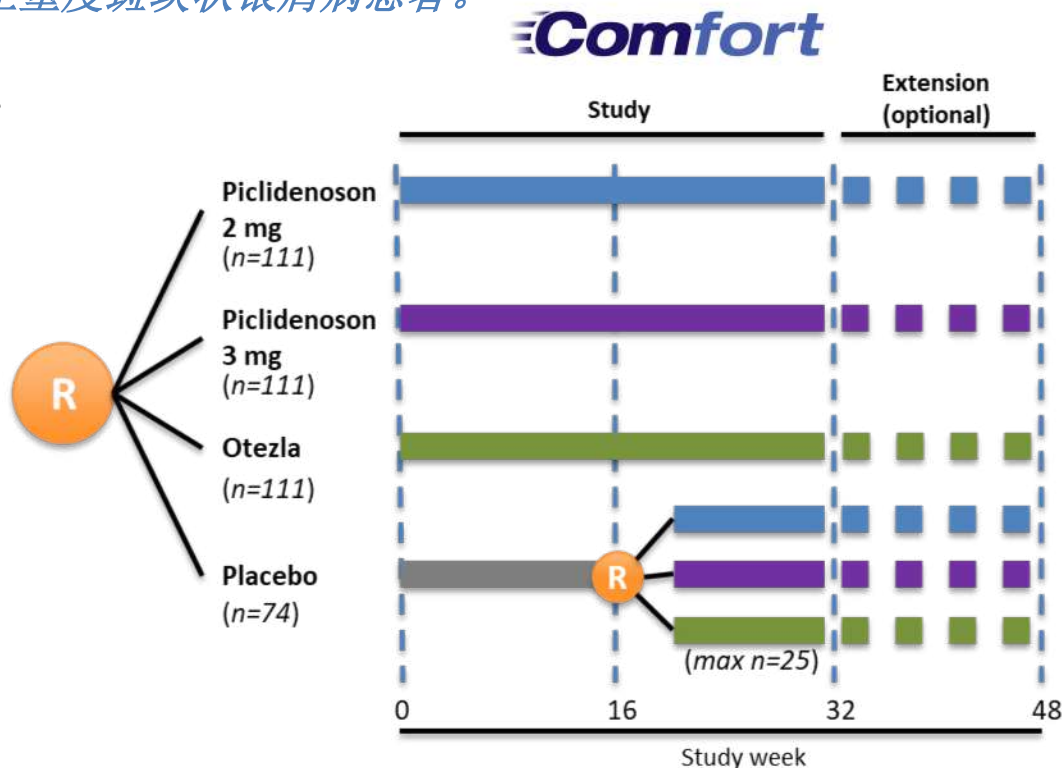
Mechanism of Action 作用机理



Psoriasis Phase III – Positive Interim Analysis Data 银屑病三期临床 - 积极的中期分析数据

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 舒适III期临床研究旨在确定Piclidenoson对安慰剂的优越性和对Otezla®的非劣效性，适用于中度至重度斑块状银屑病患者。

- Randomized, double-blind, active and placebo-controlled 随机、双盲、积极和安慰剂对照的
- Primary endpoint: PASI 75 at week 16 vs. placebo 主要终点：与安慰剂对比，第16周时PASI 75
- Secondary endpoints: non-inferiority vs. Otezla at week 32 次要终点：第32周时与Otezla的非劣效性比较
- Study duration 32 weeks; optional extension to 48 weeks 研究时间为32周；可选择延长至48周



Top Line Results Expected End of Year 预计年底发布顶线结果

COVID-19 Phase II – Treatment of Moderate/Severe Disease

治疗新冠病毒二期临床 – 治疗中度/重度疾病

- Enrolling patients under U.S. FDA protocol; IRBs approved 根据美国FDA协议招募患者; IRBs批准

Rationale 基本原理:

- Piclidenoson has **anti-inflammatory effects** proven in Phase II Psoriasis clinical studies and in an interim analysis of an ongoing Psoriasis Phase III study; the drug has **anti-viral effect** protected by U.S. patent US7589075. Piclidenoson also inhibits **cytokine release syndrome** and has an **excellent safety profile** / Piclidenoson的**抗炎作用**已在II期银屑病临床研究和正在进行的银屑病III期研究的中期分析中得到证实。该药具有**抗病毒作用**, 受美国专利US7589075保护。Piclidenoson还能**抑制细胞因子释放综合征**, 并具有**良好的安全性**。

Study Design 研究设计:

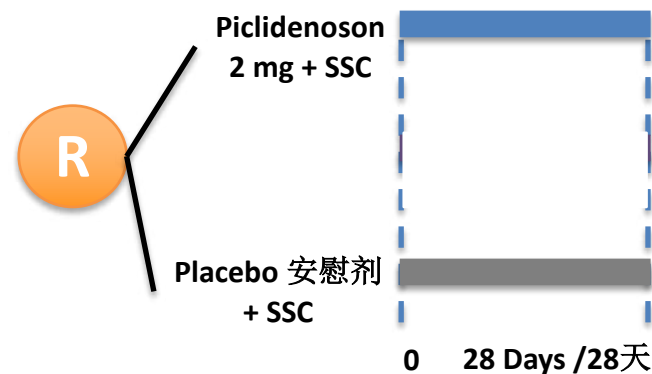
- Randomized, double-blind, placebo-controlled 随机、双盲、安慰剂对照
- 40 patients randomized 1:1 into Piclidenoson 2mg, 2x per day or placebo / 40名患者按1:1的比例随机分为两组, 一组为 Piclidenoson 2mg 每天2次, 一组为安慰剂

Primary Endpoints 主要终点

- To evaluate the benefits of treatment with Piclidenoson plus standard supportive care (SSC) vs. placebo plus SSC in hospitalized subjects with moderate/severe COVID-19 评估Piclidenoson加标准支持性护理 (SSC) 与安慰剂加SSC治疗中度/重度新冠病毒住院患者的益处。
- To evaluate the safety and tolerability of Piclidenoson 评估Piclidenoson的安全性和耐受性

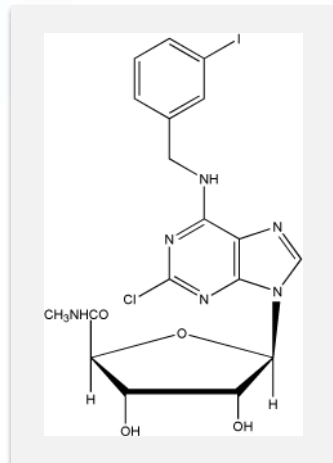
Secondary Endpoints 次要终点

- To determine the pharmacokinetics of Piclidenoson 确定Piclidenoson的药代动力学特性



Top Line Results Expected End of Year 预计年底发布顶线结果

Namodenoson – Liver Disease Drug 肝病药物



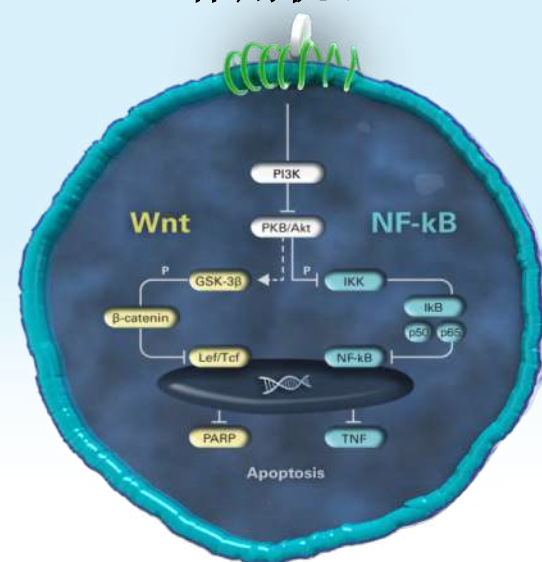
Chemical Formula
化学式

Namodenoson

Advanced Liver Cancer & NASH

晚期肝癌和NASH

Mechanism of Action 作用机理



Liver Cancer - Pivotal Phase III Under Preparation 肝癌--正在准备关键的III期临床试验

- **FDA and EMA agreed on Pivotal Phase III Study Protocol / FDA和EMA就关键性的III期研究方案达成共识**
- **Orphan Drug Status - granted by FDA and EMA 孤儿药资格--由FDA和EMA授予**
- **Fast Track Status - granted by FDA 快速通道资格--由FDA授予**
- **Compassionate Use Program - currently treating liver cancer patients in Israel 关怀使用计划--目前在以色列治疗肝癌患者**

Phase III study initiation expected Q4 2021
预计2021年第四季度启动三期研究

NASH – Phase IIa Study Successfully Concluded 成功完成IIa期研究

- **Reduced liver fat content (LFC)** 减少了肝脏脂肪含量
- **Inhibition of Fibrosis** 抑制纤维化
- **Anti-Inflammatory effect** 消炎作用
- **Decrease in body weight** 体重下降
- **Dose selection for next clinical study has been determined**
下一个临床研究的剂量选择已经确定
- **Excellent Safety** 卓越的安全性

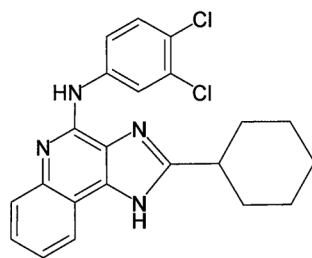
Phase IIb study expected to be initiated: Q4 2021

预计2021年第四季度将启动IIb期研究

CF602 – Erectile Dysfunction Drug 勃起功能障碍药物

Rationale: anecdotal reports from patients treated with Can-Fite's drugs, both women and men, testifying that the drugs reversed their sexual dysfunction 论据：使用Can-Fite药物治疗的病人的轶事报告，包括女性和男性。证实这些药物扭转了他们的性功能障碍。

➤ A3AR Allosteric Modulator /A3AR别构调节酶



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

➤ Properties 特性

- A3AR allosteric modulator / A3AR别构调节酶
- Molecular weight 分子量 – 411.34
- Water insoluble 不溶于水
- Orally bioavailable 口服生物可利用

➤ Significant full recovery from erectile dysfunction in diabetic rat model 糖尿病大鼠模型的勃起功能障碍得到明显的完全恢复

- Topically & Systemic 局部和全身用药
- Dose-dependent, linear effect 剂量依赖性，线性效应
- Response after single dose of CF602 单剂量CF602后的反应

➤ Novel mechanism of action 新的作用机理

- Up-regulation of eNOS and VEGF / eNOS和VEGF的上调
- Improves vasodilation and smooth muscle relaxation 改善血管扩张和平滑肌的放松

(NYSE American: CANF) (TASE:CFBI)

Cannabis Derived Pharmaceuticals 大麻衍生的药物

- **Rationale 基本原理**

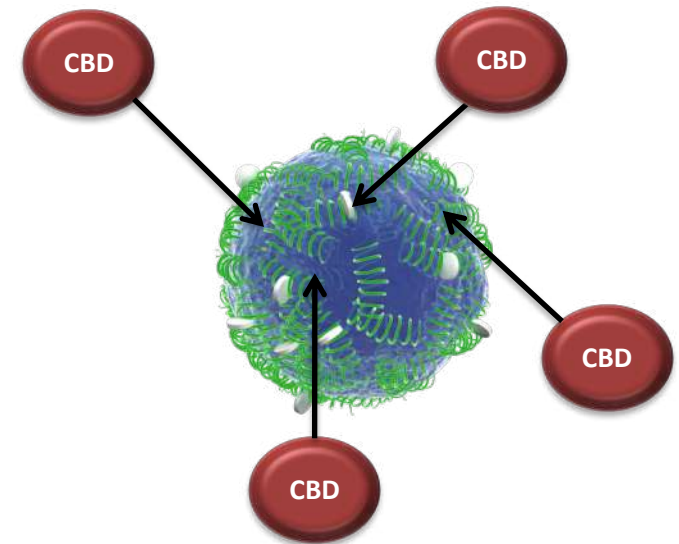
Cannabinoids induce their therapeutic effects via binding to Can-Fite's drug target, the A3 adenosine receptor 大麻素通过与Can-Fite的药物靶点--A3腺苷受体结合而诱发其治疗效果

- **Intellectual Property 知识产权**

Can-Fite filed a patent protecting the discovery of cannabinoid-based treatment of diseases where A3AR is overexpressed including liver cancer, other cancers, autoimmune inflammatory and metabolic diseases / Can-Fite申请了一项专利，保护基于大麻素治疗A3AR过度表达的疾病的发现，包括肝癌、其他癌症、自身免疫性炎症和代谢性疾病。

- **Medical cannabis market 医用大麻市场**

Projected to grow at CAGR of 29% to \$56.7B by 2026
预计到2026年将以29%的年复合增长率增长到\$567亿。 *



Summary 总结

- **Novel therapeutic approach** – unique technology for the treatment of liver and inflammatory diseases; addressing multi-billion dollar markets **新的治疗方法**--治疗肝脏和炎症性疾病的独特技术；解决数十亿美元市场规模的问题。
- **Oral drugs with proven safety and efficacy** – Piclidenoson and Namodenoson are Phase III assets in psoriasis and liver cancer; Namodenoson showed strong efficacy in a Phase II NASH study; Piclidenoson has commenced Phase II study in patients with moderate to severe COVID-19 **安全性和疗效得到证实的口服药物**--Piclidenoson和Namodenoson是治疗银屑病和肝癌的三期临床阶段资产；Namodenoson在二期临床阶段NASH研究中显示出强大的疗效；Piclidenoson已经开始对中度至重度新冠病毒患者进行二期临床阶段研究。
- **Intellectual property portfolio** – consists of 15 patent families issued and pending to protect the different indications **知识产权组合**--包括15个已颁发和正在申请的专利系列，以保护不同的适应症。
- **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 **企业伙伴关系**--已经在选定的地区授权Piclidenoson和Namodenoson，迄今已收到约\$2000万，并有可能获得另外的\$1.3亿多权利金。
- **Financially well positioned** – the company is well positioned to conduct all its clinical development programs and G&A for > 1 year **财务状况良好**--公司有能力进行所有的临床开发项目和支付一年以上的一般费用和行政费用。