UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 17, 2024

ANEBULO PHARMACEUTICALS, INC
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-40388	85-1170950
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Anebulo Pharmaceuticals, Inc. **1017 Ranch Road 620 South, Suite 107** **Lakeway, TX** **(Address of Principal Executive Offices)**	**78734** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (512) 598-0931

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ANEB**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

Anebulo Pharmaceuticals, Inc. (the "Company") has updated its Corporate Presentation, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the Corporate Presentation furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The Corporate Presentation furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished with this Current Report on Form 8-K:

Exhibit Number	Exhibit Description
99.1	Anebulo Pharmaceuticals, Inc. Corporate Presentation, dated October 17, 2024
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within in the inline XBRL document)

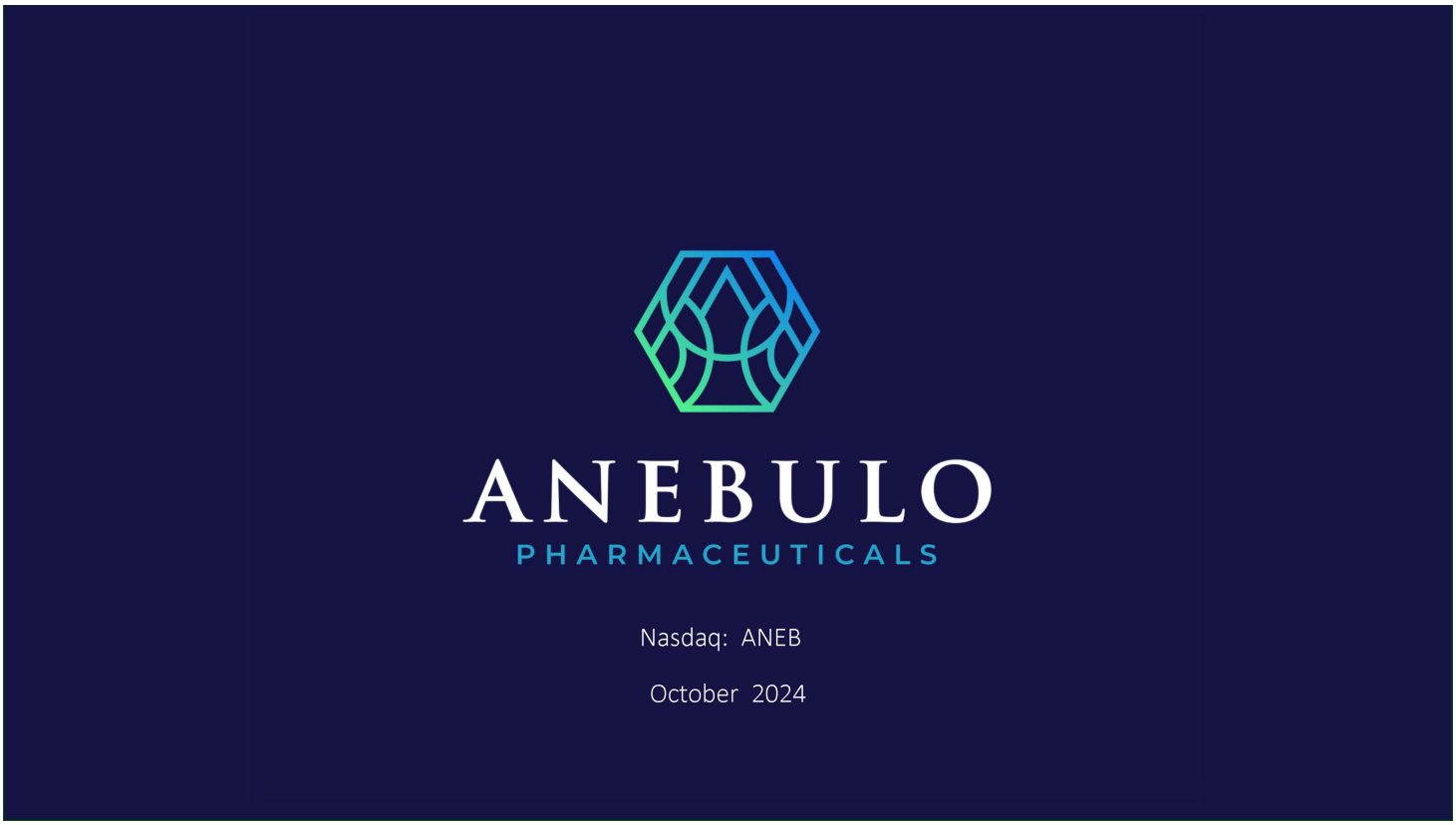
SIGNATURES

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 hereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: October 17, 2024

By: */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer (*Principal Executive Officer*)



Cautionary Note Regarding Forward-Looking Statements

Forward-Looking Statements

Statements contained in this presentation that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "designed," "expect," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the opportunity to take Selonabant into a pediatric setting, the size of the addressable market,; the potential for Selonabant to address an unmet medical need for a specific antidote for ACI and unintentional cannabis poisoning; and Anebulo's expectation that Selonabant will rapidly reverse key symptoms of ACI. You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: initial and interim results from clinical studies are not necessarily indicative of results that may be observed in the future; the ability to obtain regulatory approval; the Type B feedback should not be relied on as an indication that Selonabant will ultimately be approved; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company's business and product development plans caused by or associated with health crises or geopolitical issues; and Anebulo's need for additional capital. These and other risks are described under the "Risk Factors" heading of Anebulo's Annual Report on Form 10-K for the year ended June 30, 2024 filed with the SEC on September 25, 2024, its subsequent quarterly and other reports filed with the SEC. All forward-looking statements made in this presentation speak only as of the date of this presentation and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect new information, future events, changed conditions or otherwise after the date of this presentation.

Market & Industry Data

This document includes market and industry data and forecasts that Anebulo has developed from independent research reports, publicly available information, various industry publications, other published industry sources or Anebulo's internal data and estimates. Independent research reports, industry publications and other published industry sources generally indicate that the information contained therein was obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Although Anebulo believes that the publications and reports are reliable, Anebulo has not independently verified the data and makes no representation or warranty with respect to the accuracy of such information. Any and all trademarks and trade names referred to in this presentation are the property of their respective owners. Anebulo's internal data, estimates and forecasts are based on information obtained from trade and business organizations and other contracts in the markets in which it operates and management's understanding of industry conditions. Although Anebulo believes that such information is reliable, Anebulo has not had such information verified by any independent sources.

ABOUT US

Introducing Anebulo Pharmaceuticals

Anebulo was founded with the intention of **developing treatments for cannabis-induced toxicities,** such as unintentional cannabis poisoning, acute cannabinoid intoxication and the broader landscape of cannabis associated conditions.

We understand the burden of these diseases and are committed to addressing the unmet medical need.

Investment Highlights

ANEBULO PHARMACEUTICALS

Anebulo is a biopharmaceutical company developing treatments for unintentional cannabis poisoning and acute cannabinoid intoxication

Mechanism of Action (MOA)

Selonabant (ANEB-001) is a de-risked asset with a well-understood mechanism of action:

- Potent, small molecule antagonist with a high affinity and selectivity for the human cannabinoid receptor type-1 ("CB1")
- Demonstrated proof-of-concept in a Phase 2 THC challenge study; selonabant rapidly reversed key negative effects of cannabis intoxication

Cannabis-Induced Toxicity Pipeline

Unintentional Cannabis Poisoning - IV

- Selonabant has the potential to be first-to-market

Acute Cannabinoid Intoxication (ACI) - Oral

- Selonabant has the potential to be first-to-market

Patent Status

- Strong IP position with ***2 issued US patents and 6 patent applications*** pending in US and other territories into 2040 and beyond

Distribution Strategy

- Ultimate vision to make selonabant available prior to ED setting and eventually more accessible to patients
  - Emergency Department
  - First Responders

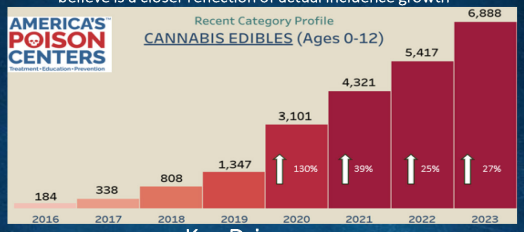
Experienced Leadership

- Management team brings a wealth of broad biopharmaceutical industry experience and years in drug discovery, development and commercialization

Cannabis-induced CNS depression in pediatric patients

Poison Center Call Data

Poison Center Calls represent a sampling of actual incidence. In particular, the below increase in calls at the poison centers represent a sampling of cases we believe is a closer reflection of actual incidence growth



Key Drivers

1. Increasing THC potency
2. Edibles consumed have delayed effect that can lead to consuming multiple doses and greater toxicity
3. Pediatric outcomes more severe due to more CB1 receptors in their brains, smaller body size, immature metabolism [3]

[3] Long LE, et al. BMC Neurosci. 2012 Jul 24;13:87. Takakuwa K et al Int J Emerg Med 2021, 14:10

Annual cannabis-associated ED visits in the U.S., in 2021 (All Ages)

Cannabis-Related ED Visits

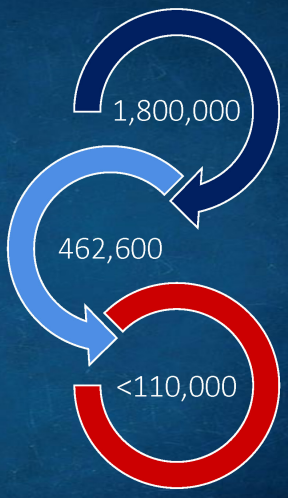
Any association with cannabis, including cases where cannabis was not the primary reason for the ED visit [1]

Cannabis- Attributable Visits

Any cannabis-induced condition whether due to acute exposure or chronic cannabis use/abuse/dependence [2]

CNS Depression

Unique serious and potentially life-threatening condition – acute cannabis induced CNS depression; majority of cases are in pediatric population (~70,000)



[1] DHHS memo, 2023; THE HCUP NATIONWIDE EMERGENCY DEPARTMENT SAMPLE (NEDS) 2020 (ahrq.gov)

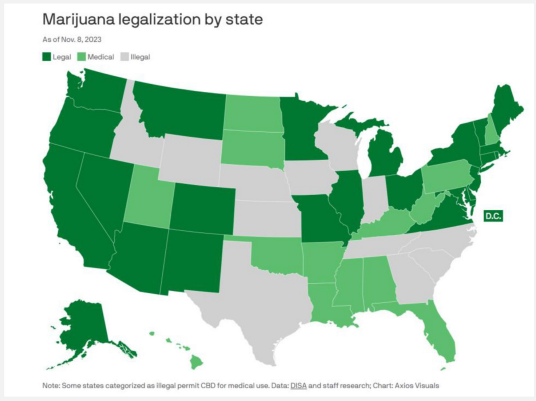
[2] Proportion attributable to cannabis and proportion treatable are based on Monte A et al, 2019

Key Drivers to Rising Incidence

The numbers

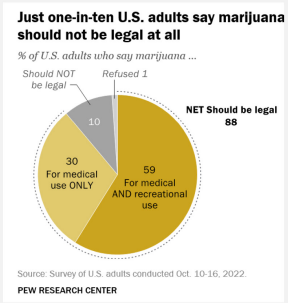
In 2022, 61.9 million people (22% of people aged 12 or older) used marijuana[1]

54% of Americans live in a state where the recreational use of marijuana is legal



https://www.axios.com/2023/11/08/pot-weed-legal-medical-marijuana

An overwhelming share of U.S. adults (88%) say that marijuana should be legal for medical and/or recreational use by adults



Schedule 1 to 3 is the first step towards federal decriminalization

[1] https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report

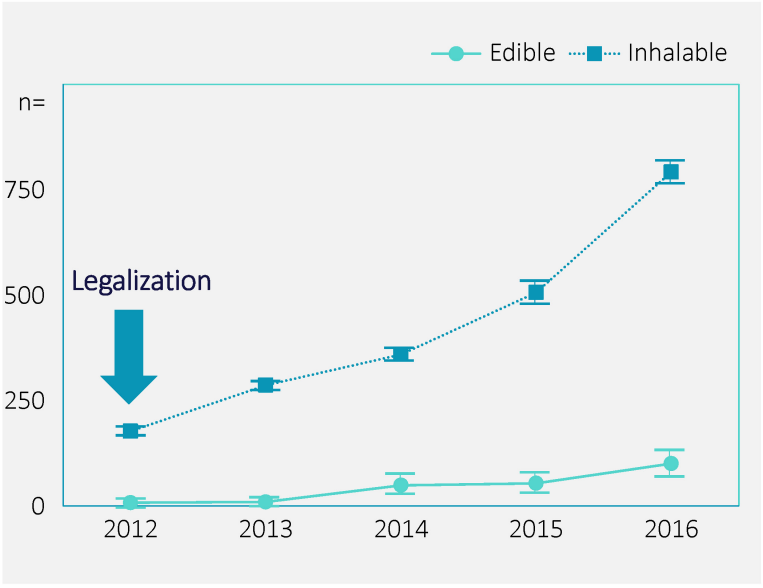
Legalization Drives ED Visits

4-year study at University of Colorado Hospital

- Cannabis-related ED visits in adults tripled after Colorado became the first U.S. state to allow recreational sales
- At one hospital alone, there were 10,000 cannabis-related visits, of which more than 2,000 were directly attributable to cannabis during the study period

- Edible products accounted for 10.7% of cannabis-attributable visits (2014-2016)
- Represented only 0.32% of total cannabis sales in Colorado (in kilograms of tetrahydrocannabinol) during study period

Source: Monte A et al. Ann Intern Med. 2019 Apr 16;170 (8):531-537



Demand for Solution

An increasing number of incidents in children has generated a demand for solution for acute cannabinoid intoxication

THE WALL STREET JOURNAL.

Hemp Gummies Are Sending Hundreds of Kids to Hospitals

Surge of THC products, vapes has states struggling to regulate the booming market

By Liz Essley Whyte
Published Dec 19, 2023

NEW YORK POST

6-year-old hospitalized after gobbling Delta-9 THC candy sold to unwitting family: 'He was in excruciating pain'

By Katherine Donlevy
Published Jan. 12, 2024, 8:41 p.m. ET

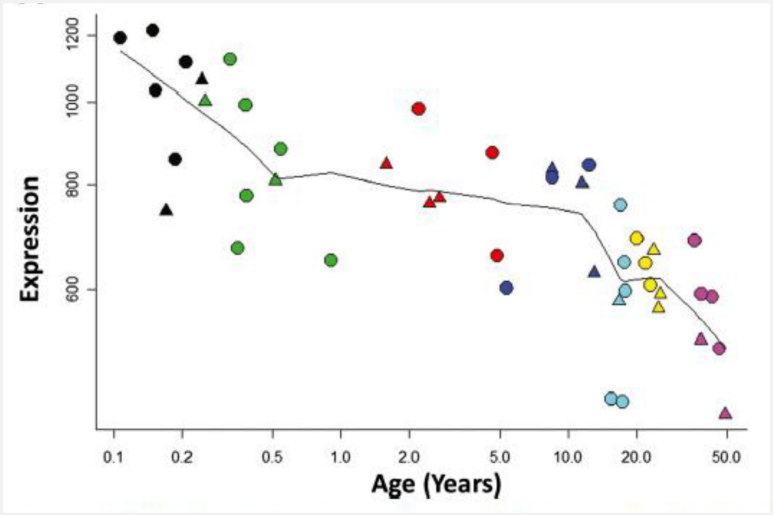
FDA Commissioner Robert Califf's comments on top FDA priorities for 2024 at JPM CERSI: (Cannabis Gummies)

"We are having a lot of issues with these. They are barely regulated and are becoming an ever-bigger problem."

Mechanism of Action, Treatment and Clinical POC

CB1 Receptor is More Abundant in the Brains of Children

Children have a greater risk of serious or life-threatening symptoms from cannabis poisoning due to a greater expression of CB1 earlier in life



Levels of CB1 are highest in brains of young children.

Abundance of the CB1 receptor declines with age and as a result, children are more sensitive to cannabis.

The gene expression-analysis *(left)* revealed a significant decrease of >50% in CB1R mRNA across the human lifespan.

*Expression of CB1 receptor in dorsolateral prefrontal cortex determined by microarray. (Long LE, et al. Developmental trajectory of the endocannabinoid system in human dorsolateral prefrontal cortex. BMC Neurosci. 2012 Jul 24;13:87) .

Currently No Approved or Standard Treatment

Currently no approved or standard treatment for acute cannabis-induced toxicity when patients present to the ED, thus physicians typically monitor and provide supportive care.

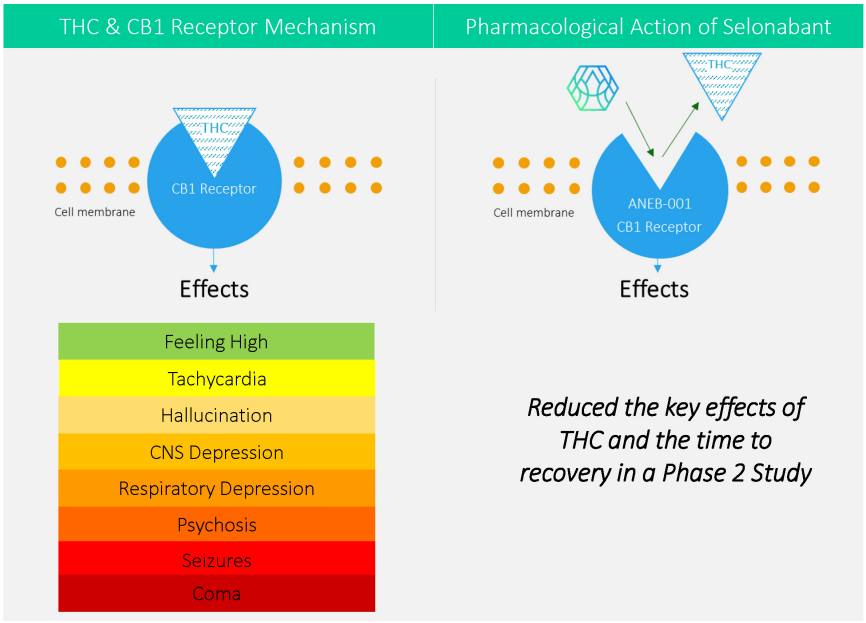
Pediatric Cannabis Poisoning Patient Journey

Initial Presentation for Care & Diagnosis	Initial Treatment	Patient Progression and Ongoing Care[1]
Patients will develop delayed symptoms after ingestion	First-Line: Most pediatric cannabis poisoning patients are observed and provided supportive care such as hydration and supplemental oxygen	Approx.40% of pediatric patients <11 years of age with cannabis poisoning are admitted to the hospital for extended observation
Patients will typical present to the emergency department and a physician will conduct an examination and assess symptoms and potential causes, including co-ingestion (ED Physician)		Approx. 20% of pediatric patients <11 years of age are admitted to critical care (ICU/PICU) with serious symptoms: CNS depression, difficulty breathing, seizures, or coma
Testing for THC may be performed with a urine tox screen or less frequently a blood test		Although rare, deaths resulting from unintentional cannabis poisoning in children have been reported

[1] Takakuwa K et al Int J Emerg Med 2021, 14:10

Intuitive Pharmacology Reduces Risk

Selonabant is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM



- Selonabant binds to the same receptor as cannabis and other cannabinoids blocking them from binding and activating
- Good bioavailability and brain penetration in animals
- Antagonizes THC-induced hypolocomotion in mice, a CB1 receptor-mediated response
- Blocked THC effects in humans in a Phase 2 study

Selonabant Clinical Development for ACI

Extensive POC with 154 subjects in Phase 2 Study where selonabant showed rapid reversal effects of THC while being well tolerated across all studies

Data Read Outs

Part A — July 2022

-Co-administered THC/selonabant

-Robust reduction in THC effects on feeling high and alertness

Part B — March 2023

-Examined range of THC/selonabant doses and delayed dosing of selonabant

-Rapid reversal of THC effects on feeling high, alertness, body sway

-Potent effects of selonabant (10 mg) against a 30 mg THC dose

Part C — August 2023

-Part C used THC doses up to 60 mg

Open label study to safely examine higher THC doses (no placebo arm)

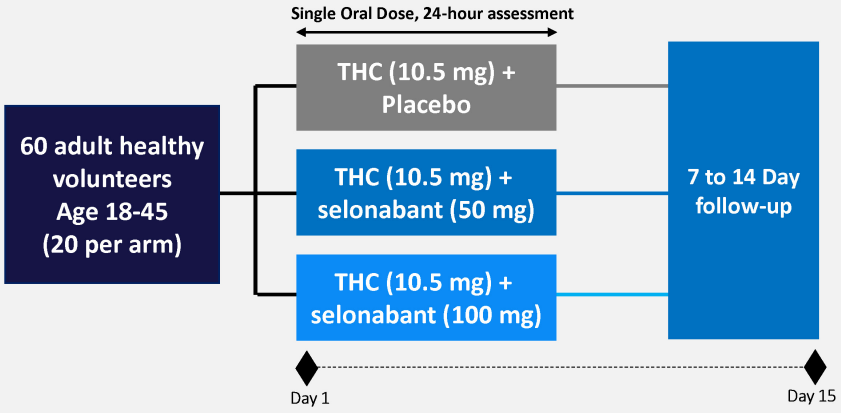
-Selonabant blocked effects of THC on alertness, body sway, heart rate, and feeling high

-Selonabant was well tolerated

Selonabant: Phase 2 Part A Study Design

Primary Objective: To investigate the ability of selonabant to inhibit the psychotropic effects of Δ9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

Randomized, double-blind, placebo-controlled study



Clinical End Points:

Primary: inhibition of central nervous system effects of THC
- Visual analog scale "Feeling High"
- Visual analog scale "Alertness"
- Body sway
- Heart rate

Secondary:
- Additional efficacy metrics safety/tolerability
- Pharmacokinetics
- Pharmacokinetic-Pharmacodynamic correlations

Selonabant: Phase 2 Part B Study Design

Part B Study Design

Six sequential cohorts (N = up to 15; 2:1 active/placebo) to examine effect of higher THC doses, lower selonabant doses, timing of selonabant, and food

Cohort	*THC Dose (mg)*	*Selonabant Dose (mg)*	*Dosed with THC*	*Dosed 1hr after THC*
1	21	30	X	
2	21	10	X	
3	21	10		X
4	40*	10		X
5	30	10		X
6	30 (Fed)**	10		X

Cohorts 1-3 used THC tablets (Namisol®). Cohorts 4-6 used THC capsules (Marinol®).
*Cohort not completed due to poor THC tolerability. **Following a high fat meal.

Primary Outcomes

VAS Feeling High, VAS Alertness, Body Sway, Heart Rate

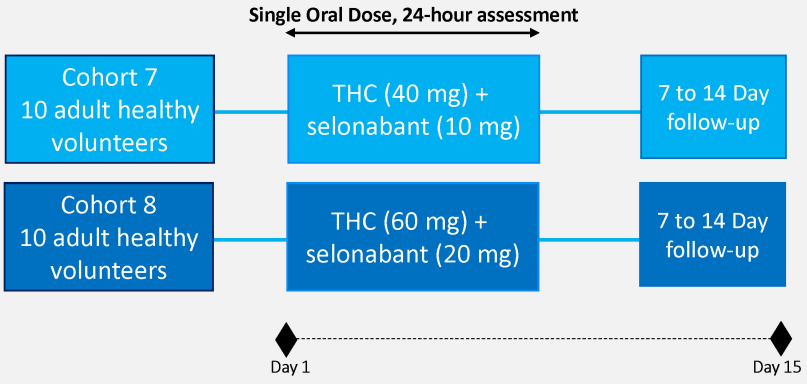
Secondary/ Exploratory Outcomes

Safety, Tolerability, Pharmacokinetics (selonabant, THC, THC metabolites), additional subjective effects

Selonabant: Phase 2 Part C Extension - Higher THC Doses

Primary Objective: Safety and Efficacy of selonabant as a treatment for Intoxicating Effects of Δ9-Tetrahydrocannabinol (THC) in Healthy Adult Volunteers.

Open-label Study, Simultaneous Dosing of THC/Selonabant



Clinical End Points:

- Global: CGI-S
- Cognitive: Verbal Learning Test
- Psychomotor: Finger tapping
- Subjective: VAS Feeling High
- Subjective: VAS Drug Effect
- Body sway/gait: Timed up and go with accelerometer
- Psychiatric Symptoms
- Objective: Heart rate

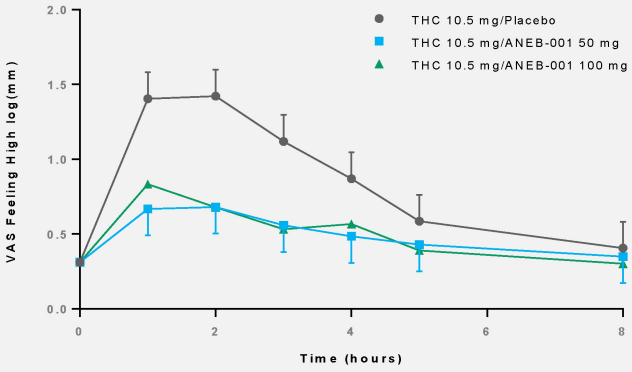
Safety/tolerability, PK, PK/PD correlations

Selonabant: Sustained Reduction of Feeling High

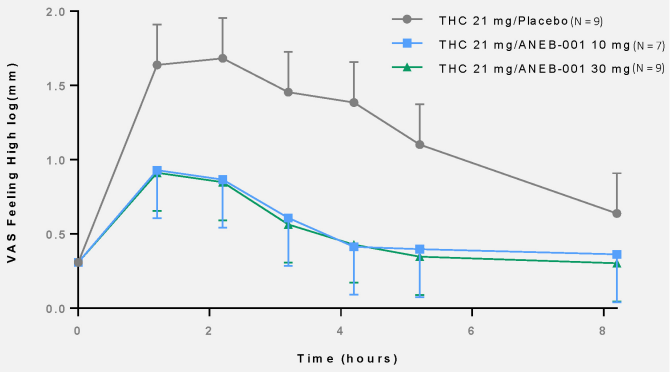
Selonabant (ANEB-001) produced sustained and substantial reduction of feeling high during coadministration ($p < 0.001$)

Time Course of VAS Feeling High Following Coadministration of THC and selonabant

10.5 mg THC (Part A) (N = 20/arm)



21 mg THC (Part B)



Outcomes:

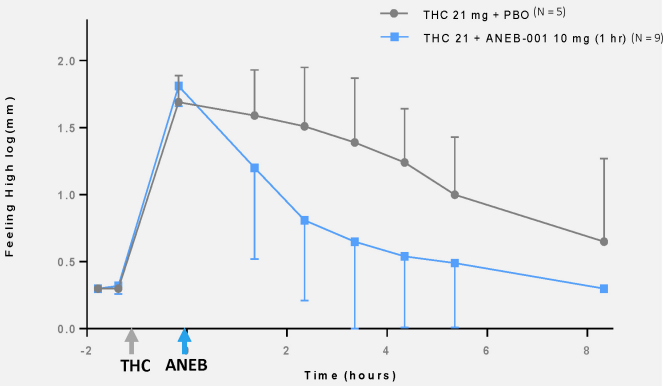
- THC/placebo produced a substantial increase in the VAS feeling high score
- The selonabant protection was sustained for the duration of the THC effect
- The lowest dose of selonabant tested (10 mg) blocked THC effect despite using a higher THC dose

Delayed Dosing: Rapidly Reversed THC Effect

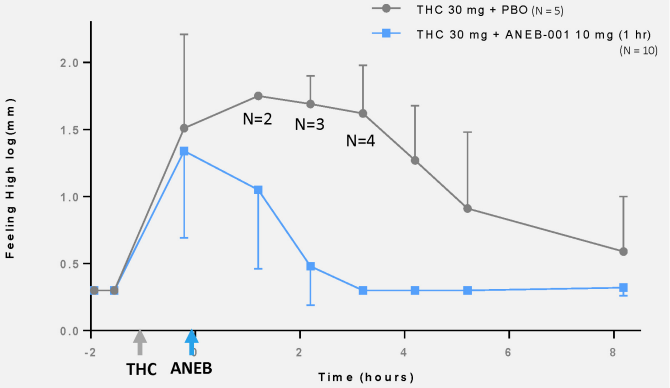
Selonabant (ANEB-001) produced sustained and substantial reduction of feeling high during coadministration ($p < 0.001$)

Time Course of VAS Feeling High After THC with Delayed Dosing of selonabant

21 mg THC (Part B)



30 mg THC (Part B)



Outcomes:

- Oral THC (21 to 30 mg) induced strong feeling high symptoms in all subjects
- Delayed dosing of selonabant rapidly reversed feeling high compared to placebo
- Selonabant reduced recovery time by several hours even after a 30 mg THC dose

Strategic Summary: Selonabant

Insights Overview

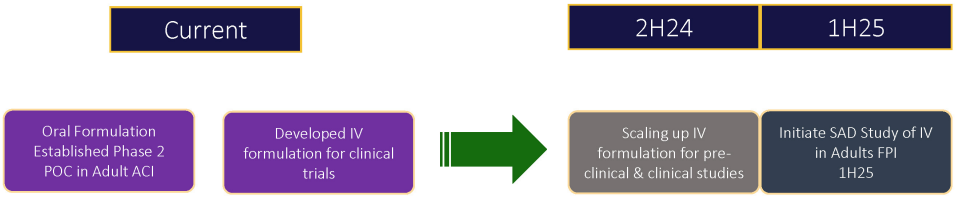
- Selonabant has a well-understood mechanism of action as a potent, small molecule CB1 antagonist with a high affinity for the human CB1 receptor
- Established proof-of-concept in a Phase 2 THC challenge study; oral selonabant was well-tolerated and rapidly reversed key negative effects of cannabis intoxication
- Selonabant IV provides opportunity to take selonabant into pediatric setting

Next Steps

- Focus on an IV product for the most serious cases including cannabis-induced CNS depression in pediatric patients
- Initial clinical formulation selected – scaling up for tox studies and initial clinical trial in adults in 1H25

Key Milestones for Intravenous Selonabant

Outlined below are projected key target milestones starting in 2024 and providing a roadmap through 1H2025



Events are listed by calendar year timelines

Leadership

Executive Management & Team

Richie Cunningham

Chief Executive Officer

Over 25 years of successful leadership experience spanning pre-IND drug discovery, clinical development, and commercialization of pharmaceutical products with various companies. Blockbuster drugs include Jardiance, Ofev, and Pradaxa.

Ken Cundy, PhD

Chief Scientific Officer

Broad experience in drug discovery, preclinical and clinical development, and product approval spans more than 30 years with various companies and includes blockbuster drugs such as Gilead's HIV drug tenofovir and the filing of more than 15 INDs and 6 NDAs

Outsourced model with highly capable and efficient external support:

CMC, Regulatory, IP, Pre-clinical, Clinical Operations, Clinical Science

Board of Directors

Joseph Lawler	Richie Cunningham	Aron English	Jason Aryeh	Areta Kupchyk	Nat Calloway	Ken Lin	Bimal Shah
Founder, Chairman	*Chief Executive Officer*	*Independent Director*	*Independent Director*	*Independent Director*	*Independent Director*	*Independent Director*	*Independent Director*
General Partner JFL Capital Management	CEO Anebulo, former CEO Tyme, former CEO Icagen, Boehringer Ingelheim, Bausch Health	General Partner 22NW	General Partner JALAA Equities, Board Member Ligand Pharmaceuticals	FDA lawyer, Former Partner Foley Hoag, former Associate Chief Counsel for Drugs and Biologics at FDA	Analyst and Partner 22 NW Cornell University and Columbia University	Former CEO Ab Initio Biotherapeutics, former VP of Corporate Development and IR at Ulthera	Former CFO, Corium, former SVP Corporate Finance and Strategy, Sumitovant, former Goldman Sachs, J.P. Morgan, and Warburg Pincus. Stanford University.