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): September 26, 2022

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.)**

1415 Ranch Road 620 South, Suite 201 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.

As previously announced, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), will host its inaugural R&D Day on Monday, September 26, 2022, in person at the Nasdaq MarketSite in New York City from approximately 10:00 a.m. to 12:30 p.m. (ET). During the R&D Day, the Company plans to present the Company presentation furnished as Exhibit 99.1 to this report.

The information under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On September 26, 2022, the Company announced positive interim data from Part B of its Phase 2 clinical trial of ANEB-001 for the potential treatment of acute cannabinoid intoxication ("ACI"). The clinical trial is being conducted in healthy adult occasional cannabis users at the Centre for Human Drug Research ("CHDR") in the Netherlands. Results of Part A of the study, announced in July 2022, showed positive effects of 50 mg or 100 mg of ANEB-001 in reducing the effects of a 10.5 mg oral delta-9-tetrahydrocannabinol ("THC") dose. Part B of the study is an adaptive study design intended to evaluate lower doses of ANEB-001 at higher levels of THC.

The first two cohorts of Part B were challenged with 21 mg of THC, dosed orally (twice the THC dose used in Part A). Subjects then received 30mg (Cohort 1) or 10mg (Cohort 2) oral doses of ANEB-001, or matching placebo. The interim data available from Part B include pharmacokinetics ("PK"), key pharmacodynamic ("PD") outcomes, and blinded safety data. Based on these data, subjects challenged with a higher 21 mg oral THC dose and treated with placebo showed greater central nervous system effects than observed in Part A with 10.5 mg THC. The effects included a substantial increase in feeling high and body sway, decreased alertness, and slightly increased heart rate compared to baseline. In contrast, dosing of subjects with 10 mg or 30 mg ANEB-001 led to significant and sustained reductions in the visual analog scale ("VAS") feeling high

score ($p < 0.001$), improvement in the VAS alertness scale ($p < 0.01$), and a reduction in THC-induced body sway ($p < 0.01$), compared to placebo.

In addition, 100% of subjects given 21 mg THC with placebo in Cohorts 1 and 2 met the VAS threshold for feeling high (>20 mm on the 100 mm VAS scale) compared to only 1 subject per group dosed with ANEB-001 at 10 mg or 30 mg doses. Although the THC-induced increase in heart rate in this study was small, there was a trend towards improvement with ANEB-001 compared to placebo. The 10 mg and 30 mg ANEB-001 doses had similar effects to previous higher doses used in Part A, despite doubling the THC dose. Pharmacokinetic data from Part A and the first two cohorts of Part B confirmed rapid absorption and dose-related plasma exposure for oral ANEB-001.

Based on blinded safety data, adverse events in Cohorts 1 and 2 were mild and transient, except for two cases of moderate dizziness in Cohort 1 likely attributable to THC.

Based on Part A and interim Part B results, the Company is continuing Part B of the study at CHDR to further evaluate the dose response and the effects of separating the doses of THC and ANEB-001. Enrollment of the third cohort of Part B is ongoing. The Company is currently collaborating with the Model-Informed Drug Development ("MIDD") group at the U.S. Food and Drug Administration to develop a PK/PD model that will be designed to predict optimal doses for treatment of ACI subjects. Preparations are ongoing for an observational study in ACI subjects in the emergency department setting to further support the PK/PD model and ANEB-001 development.

Forward-Looking Statements

Statements contained in this report 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," "believe," "designed," "expect," "intend," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the PK/PD model the Company is developing in collaboration with MIDD and its expected design and capabilities; the Company's planned observational study in ACI subjects in the emergency department setting and its expected benefits; and statements related to the remainder of Part B of the Phase 2 study. 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; clinical trial site challenges that may impact the expected timing of the Company's ongoing clinical trials, including challenges related to COVID-19; the timing and success of clinical trials and potential safety and other complications thereof; future supply or manufacturing issues; any negative effects on the Company's business and product development plans caused by or associated with COVID-19 or geopolitical issues; and the Company's need for additional capital. These and other risks are described in under the "Risk Factors" heading of the Company's most recent annual report on Form 10-K filed with the Securities and Exchange Commission on September 9, 2022. All forward-looking statements made in this report speak only as of the date of this report and are based on management's assumptions and estimates as of such date. Except as required by law, the Company 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 report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Company Presentation dated September 26, 2022
104	Cover Page of Interactive Data File (embedded within 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: September 26, 2022

By: */s/ Simon Allen*
Simon Allen
Chief Executive Officer

Exhibit 99.1


ANEBULO
PHARMACEUTICALS
NASDAQ: ANEB
Inaugural R&D Day
September 26, 2022

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," "believe," "designed," "expect," "intend," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: market opportunities and growth in these markets; the PK/PD model we are developing in collaboration with MIDD and its expected design and capabilities; the potential of ANEB-001 to treat ACI; the planned observational study in ACI subjects in the emergency department setting and its expected benefits; statements related to the remainder of Part B of the Phase 2 study; the potential regulatory pathway for ANEB-001; our expectation that the pharmacology of ANEB-001 will support a single dose product; drug product manufacturing; and ANEB-001 parenteral product development. 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; clinical trial site challenges that may impact the expected timing of Anebulo's ongoing clinical trials, including challenges related to COVID-19; the timing and success of clinical trials and potential safety and other complications thereof; future supply or manufacturing issues; our ability to successfully commercialize and distribute ANEB-001, if approved; any negative effects on Anebulo's business and product development plans caused by or associated with COVID-19 or geopolitical issues; and our need for additional capital. These and other risks are described in under the "Risk Factors" heading of Anebulo's most recent annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on September 9, 2022. 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 presentation 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 warrant with respect to the accuracy of such information. Any and all trademarks and tradenames 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.

Today's Agenda

- Introduction: Dr. Joseph Lawler, MD, PhD, Chairman of the Board
- Corporate Overview: Simon Allen, Chief Executive Officer
- Clinical Program Highlights and Progress Updates: Dr. Ken Cundy, PhD, Chief Scientific Officer
- Q&A Session
- Concluding Remarks: Simon Allen, Chief Executive Officer

Introductory Remarks

Dr. Joseph Lawler, MD, PhD, Founder and Chairman of the Board

Corporate Overview

Simon Allen, Chief Executive Officer

Anebulo overview

- Biopharmaceutical company developing novel antidote for acute cannabinoid intoxication and, longer term, other indications related to abuse and addiction
- ANEB-001 has the potential to reverse the negative effects of acute cannabinoid intoxication within one hour of administration
  - Potent, small molecule CB1 antagonist with a high affinity for the human CB1 receptor
  - Positive topline (Part A) and interim (Part B) data comparing ANEB-001 to placebo in healthy subjects challenged with THC
  - Significant improvement in key symptoms of THC intoxication
  - Completed clinical trials demonstrate ANEB-001 is rapidly absorbed and well tolerated
- May 6, 2021 IPO raised gross proceeds of $21 million

Value highlights

Potential to address unmet medical need to treat acute cannabinoid intoxication, a large and growing market

- No product is approved for this indication and no other compound is further along in clinical testing
- In 2019, ~1.7 million cannabinoid-related emergency department (ED) visits in the U.S., growing 15% annually
- Legalization of cannabis for medical and recreational use is driving intoxications and hospital ED visits

ANEB-001 has a well-understood mechanism of action

- In-licensed from Vernalis/Ligand Pharmaceuticals
- Central effects of THC are CB1 mediated and ANEB-001 is a CB1 antagonist
- Rapidly absorbed, well tolerated and crosses the blood-brain barrier

Rapid path to proof-of-concept

- Positive Phase 2 human proof-of-concept data (Part A complete, Part B continues)
- Study being conducted in the Netherlands (experienced with these type of trials)

Capital-efficient business model

- Outsourcing clinical research and data management
- Exploring strategic collaborations for commercialization
- Rapid clinical trials matched with a lean corporate structure

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ANEB-001 for Acute Cannabinoid Intoxication

Acute Cannabinoid Intoxication

- Over 140 million people use cannabis worldwide
- In U.S., decriminalization of marijuana by states has led to an increase in reports to poison control centers and in cannabis-related ED visits
  - Catalyzed by excessive use in adults and inadvertent ingestions in small children
  - Synthetic cannabinoids are the most abused synthetic drug and the second most abused drug among adolescents
- Duration of toxicity
  - Inhalation lasts 2-6 hours
  - Ingestion lasts approximately 8-12 hours

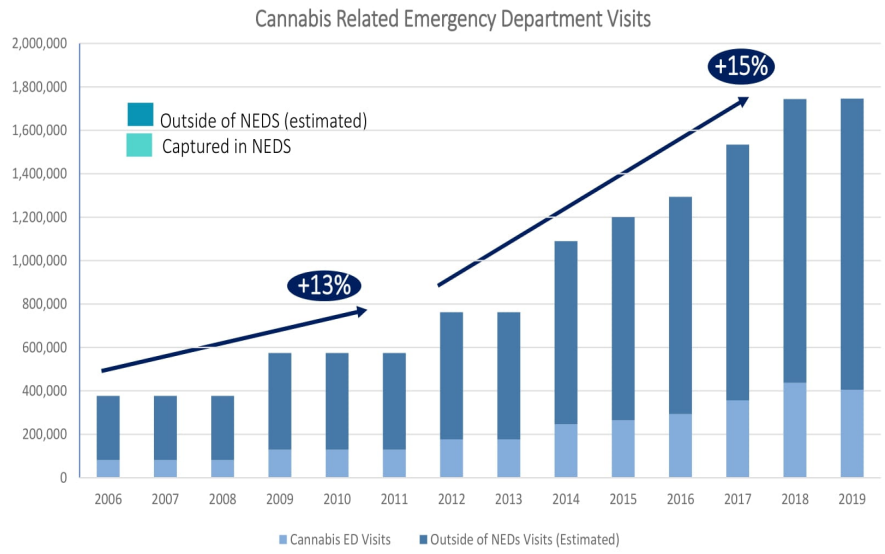
Symptoms of Acute Cannabinoid Intoxication

- Physiological effects include decreased systemic vascular resistance, elevated heart rate, decreased intraocular pressure, nystagmus, conjunctival injection, lethargy, decreased concentration and generalized psychomotor impairment
- Synthetic cannabinoid toxicity symptoms include sympathomimetic toxicity, psychosis and agitation, as well as seizures and sedation
- Severe cases have experienced hyperthermia, rhabdomyolysis and renal failure
- In children can lead to decreased muscle coordination, lethargy, seizures, dulled senses and death

Source: *Cannabinoid Toxicity.* https://www.ncbi.nlm.nih.gov/books/NBK482175/

Number of cannabis-associated ED visits is large with accelerated growth

Annual cannabis-associated ED visits in the U.S., 2006-2019



Growth of cannabis-associated emergency department visits has accelerated to a 15% CAGR since the first states legalized cannabis in 2012

We believe that

over 1.7M

ED visits in 2019 were associated with cannabis

Note: Between 21% and 23% of all emergency department visits were captured by the National Emergency Department Sample (NEDS) in the years 2006-2014. The number of visits outside of the NEDS sample was extrapolated. Source for 2006-2014: Shen, J. J., Shan, G., Kim, P. C., Yoo, J. W., Dodge-Francis, C., & Lee, Y.-J. (2018). Trends and Related Factors of Cannabis-Associated Emergency Department Visits in the United States. Journal of Addiction Medicine, 1. doi:10.1097/adm.0000000000000479, Source for 2015-2018: Company analysis of NEDS database

Marijuana legalization is increasing

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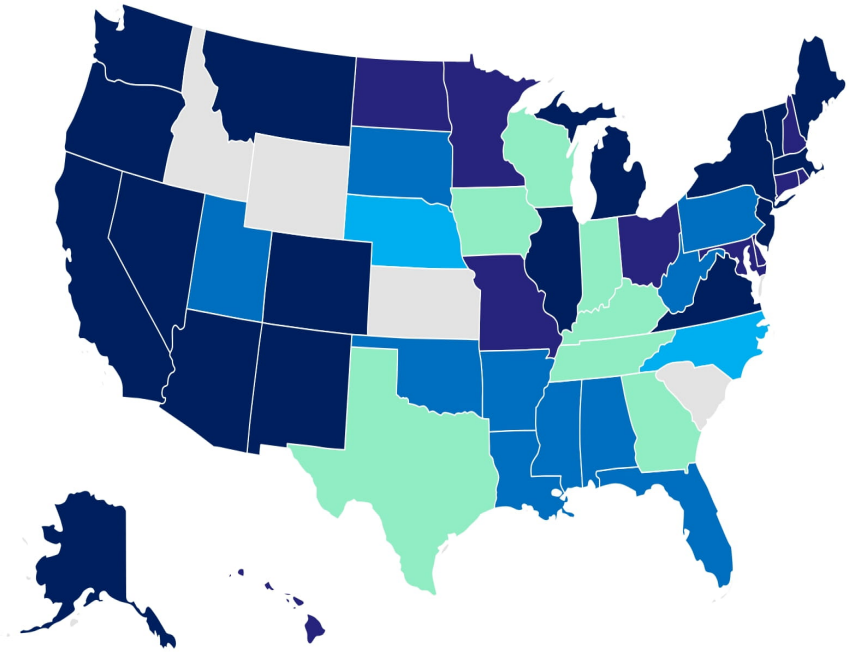
Legalized | Medical and Decriminalized | Medical | Decriminalized | CBD only | Fully illegal



Since 2012, recreational marijuana has gone from legal in no states to legal in 19 states

Marijuana is legal for medical use in 37 states

https://disa.com/map-of-marijuana-legality-by-state

Potency of edibles tends to be deceiving

Manufactured and packaged as familiar products to consumers, including candy bars or gummy snacks

- Consumers often approach cannabis edibles with the same serving size expectations as non-cannabis products
- Cannabis candy bar may contain 4x or more a safe dose of THC, much higher than a consumer may expect

Children are particularly vulnerable to intoxication given lower body mass and lack of awareness

- Poses a unique risk for pediatric exposure with brightly colored packaging and formulation into flavored candies and other sweets
- National Poison Data System call volumes increased 30% in pediatric-related calls in states post-legalization

Peak plasma THC concentrations occur in 3-10 minutes with inhalation versus 2-4 hours with ingestion

- Delayed reaction increases the risk of intoxication with edibles, particularly for inexperienced users
- Homemade edibles where dosing may be unexpectedly strong is another common cause of intoxication

Promising potential solution for acute cannabinoid intoxication

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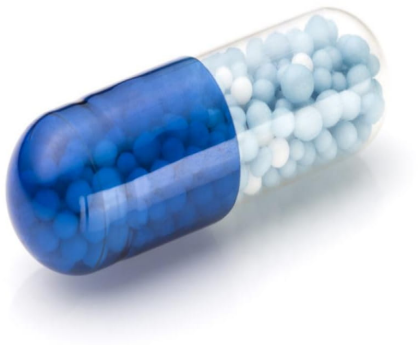
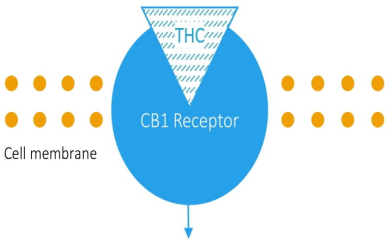
ANEB-001

- **CB1 antagonist**. Blocks the effect of THC at the CB1 receptor. Well-understood pharmacology.
- **Oral bioavailability**. ANEB-001 is administered as an oral treatment in the form of a pill, capsule or tablet.
- **Rapid absorption**. ANEB-001 is believed to rapidly reverse the signs and symptoms of acute cannabinoid intoxication in as little as 1 hour.
- **Low likelihood of drug-drug interactions**. Preclinical testing demonstrated that ANEB-001 did not inhibit the metabolic cytochromes 1A2, 2C9, 2C19, 2D6 and 3A4 at pharmacologically relevant concentrations.
- **Differentiated treatment option**. Not aware of any competing products to reverse the symptoms of acute cannabinoid intoxication that are further along in the development process than ANEB-001.

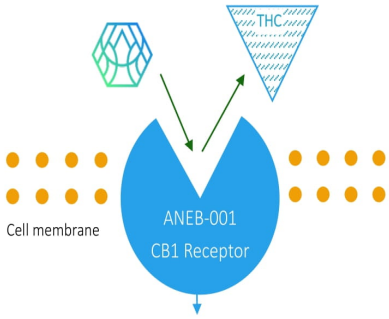


Well-understood pharmacology



Potential Effects

Feeling high
Reduction in alertness
Body Sway
Tachycardia



Potential Effects

Decrease in feeling high
Inhibit reduction in alertness
Reduction of body sway
Normalization of heartbeat

ANEB-001 is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM

Good bioavailability and brain penetration (brain:plasma ratio = 1.5)

Antagonizes THC-induced hypolocomotion in mice, a CB1 receptor-mediated response

Phase 2 proof-of-concept trial design

- N = up to 150 subjects
  - Part A included 60 subjects, 20 healthy volunteers (HV) randomized to 50mg and 100mg doses of ANEB-001 or placebo
  - Ongoing Part B expected to include 6 cohorts of 15 healthy subjects (10 active and 5 placebo) evaluating lower doses of ANEB-001 in healthy subjects that are challenged with higher doses of THC
  - Part B to explore delayed dosing to better understand real-world conditions
- Endpoints:
  - 1° inhibition of primary central nervous system effect of THC
    - Visual analogue scale "Feeling High," visual analogue scale "Alertness," body sway, heart rate
  - 2° additional efficacy metrics, PK, safety/tolerability, PK/PD correlation

ANEB-001: Next Steps

Development

- Continue Part B to explore lower ANEB-001 doses and higher THC challenge doses
- Discussions ongoing with FDA's Model-Informed Drug Development team
- Preparation for a US observational study in ACI subjects to support PK/PD model development and dose selection

Commercial

- Continued market analysis
  - Competitive landscape / Target Product Profile
  - Evolving commercial opportunity
- Expand IP position
- Explore different routes of administration and Animal Health / Canine ACI

Development plan

H1 CY22 Readout

Lifecycle management

Proof of-Concept

- Phase 2 study at single site in Netherlands
- Up to 150 healthy volunteers
- THC + doses of ANEB-001 or placebo

Pivotal Program

- FDA pre-IND meeting provided valuable guidance on U.S. regulatory path

New Drug Application

- Exploration of strategic options for rights outside of the U.S.

Intellectual Property Portfolio

- Method of use patent
  - Issued October 2021
  - Protection through 2040
- Strategy to enhance IP portfolio

In summary

Addressing unmet medical need in a large and growing market, with acute cannabinoid intoxication becoming an increasingly widespread health issue

ANEB-001 has a well-understood mechanism of action as a CB1 antagonist

Phase 2 proof-of-concept study continues

Part A Complete, Part B ongoing

Capital-efficient business model

ANEB-001 Development Update

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Dr. Ken Cundy, PhD, Chief Scientific Officer

ANEB-001 Clinical Development for ACI - Update

Phase 2 Part A Proof of Concept: New PK data, additional post-hoc efficacy data

Ongoing Phase 2 Part B Extension: 2 cohorts completed - interim PK/PD/safety update

Plans for Completion of Part B: Cohort 3 initiated – 6 cohorts total for PK/PD modeling

Regulatory Update: Discussions ongoing with FDA/MIDD

Planned First US Clinical Study: Observational study in ACI patients

Path to Potential Approval: To be finalized after Phase 2 study is completed

Parenteral Product: Prototype formulations in development for preclinical testing

ANEB-001 Development for ACI: Background

- Potent CB1 receptor antagonist
- Oral bioavailability and half-life expected to support single dose product
- Extensive Phase 1 PK data from previous development studies

- More than 140 subjects have been dosed with oral ANEB-001 to date: 80+ in Phase 1 and 50+ in Phase 2
- Well tolerated after dosing for up to 4 weeks in Phase 1 - no serious AEs
- All Phase 2 Part A adverse events mild and transient except one case of moderate nausea/vomiting

- Positive proof of concept data in Phase 2 Part A THC challenge study
- Substantial reduction in feeling high, reduction in THC-induced effects on body sway/heart rate
- Improved alertness
- Data supported testing lower doses of ANEB-001 and a higher dose of THC

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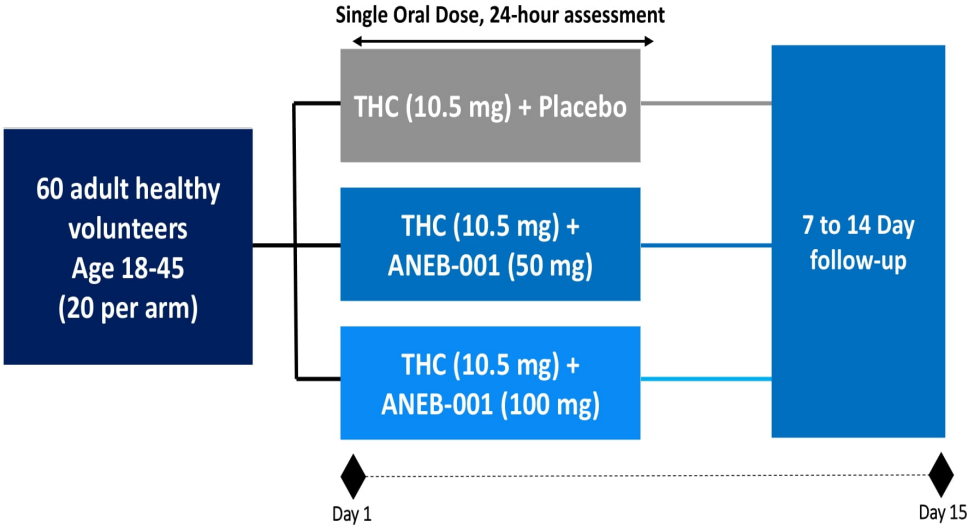
ANEB-001 Phase 2 Proof of Concept Clinical Trial

Study Title:	A randomized, double-blind, placebo-controlled study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses of CB1 antagonist ANEB-001 in healthy occasional cannabis users
Primary Objective:	To investigate the ability of ANEB-001 to inhibit the psychotropic effects of Δ9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.
Study Design:	Randomized, double-blind, placebo-controlled study in two parts. Healthy subjects challenged with an oral dose of THC and treated with ANEB-001.
Part A:	Proof of concept – completed, positive topline data released
Part B:	Extension of dose selection – ongoing (first 2 cohorts completed and third initiated)
Study Site:	Center for Human Drug Research (CHDR), Leiden, Netherlands
Clinicaltrials.gov:	NCT05282797

ANEB-001: Clinical Trial Design – Part A Challenge Study

Primary Objective: To investigate the ability of ANEB-001 to inhibit the psychotropic effects of Δ9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

Randomized, double-blind, placebo-controlled study



Endpoints:

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, PK, PK/PD correlations

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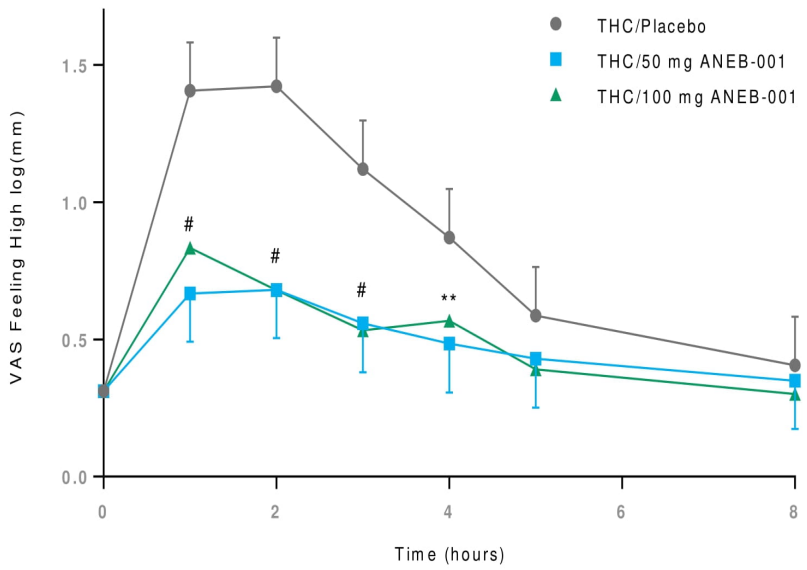
ANEB-001: Produced Sustained Reduction of Feeling High

Time Course of VAS Feeling High



- Administration of 10.5 mg oral THC alone produced a substantial increase in the VAS feeling high score
- Coadministration of THC with ANEB-001 led to a substantial reduction in feeling high compared to THC alone (overall $p < 0.0001$)
- The effect of ANEB-001 in reducing feeling high was sustained for the duration of the THC effect
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

# $p < 0.0001$ for both dose levels

**$p < 0.01$ for 50 mg, $p < 0.05$ for 100 mg

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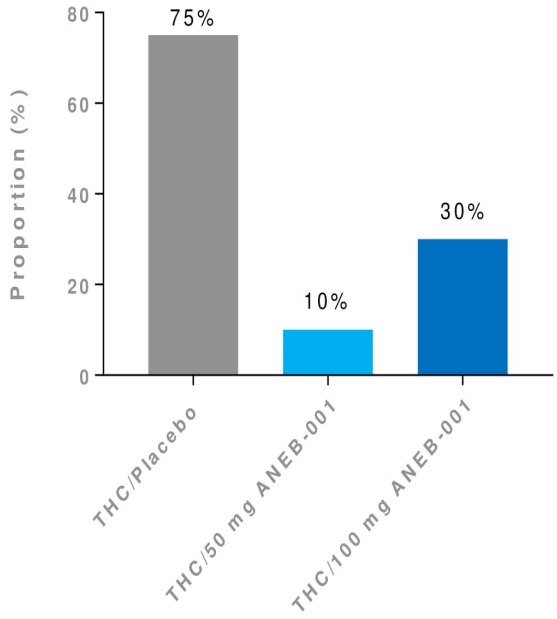
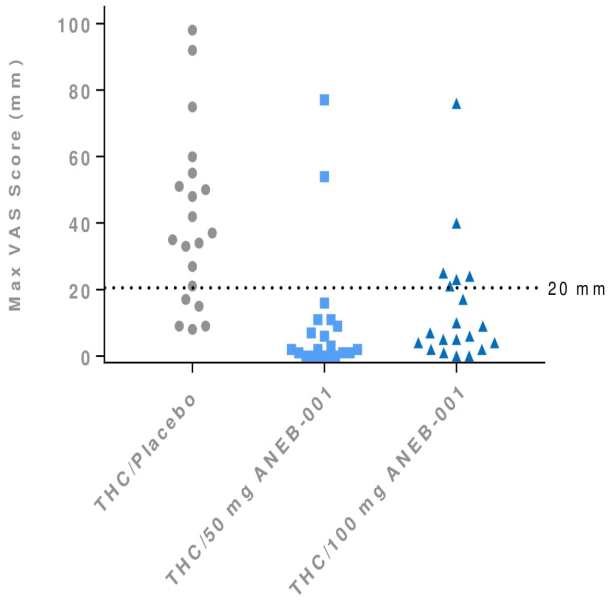
ANEB-001: Subjects Feeling High (VAS 20 mm)

Proportion of Subjects Reporting Feeling High*



Maximum VAS Feeling High Scores (mm)



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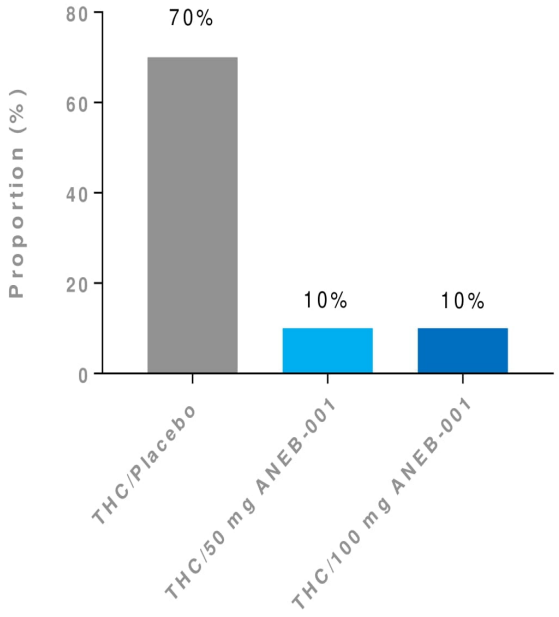
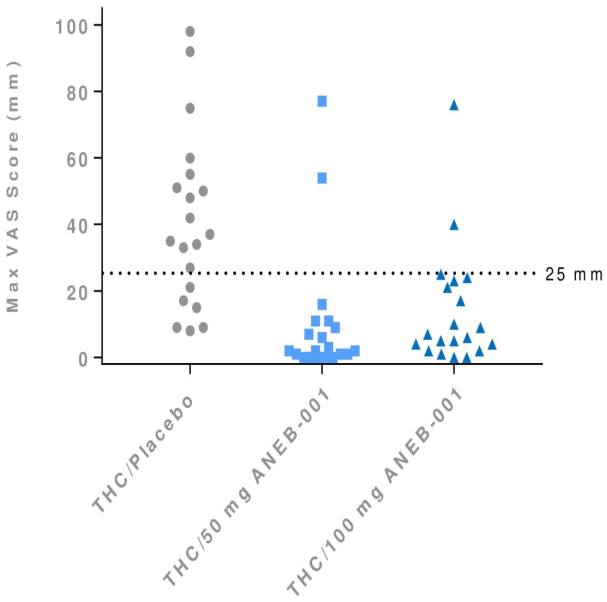
* Maximum VAS recorded during study > 20 mm (pre-specified cut-off)

ANEB-001: Subjects Feeling High (VAS >25 mm)

Proportion of Subjects Reporting Feeling High*



Maximum VAS Feeling High Scores (mm)

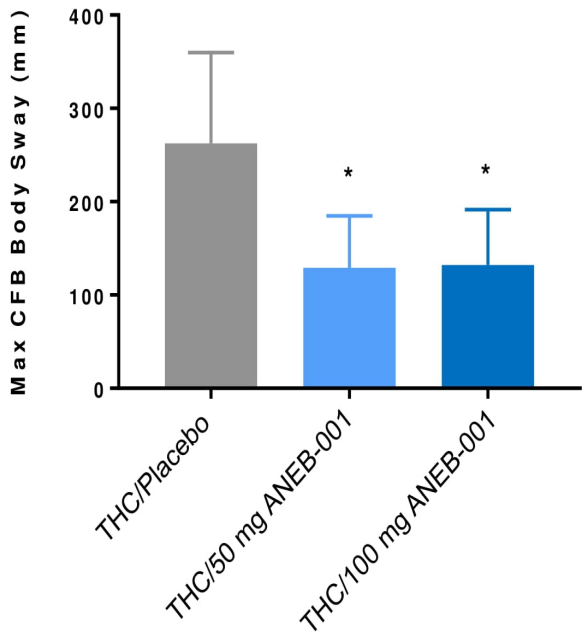


ANEBULO PHARMACEUTICALS

* Maximum VAS recorded during study > 25 mm

ANEB-001 Reduced THC-Induced Body Sway

Maximum Change from Baseline in Body Sway



- Administration of 10.5 mg oral THC alone produced an increase in body sway over 8 hours
- ANEB-001 showed a significant reduction in the maximum change from baseline for body sway
- The 50 mg dose of ANEB-001 produced a similar effect to the 100 mg dose

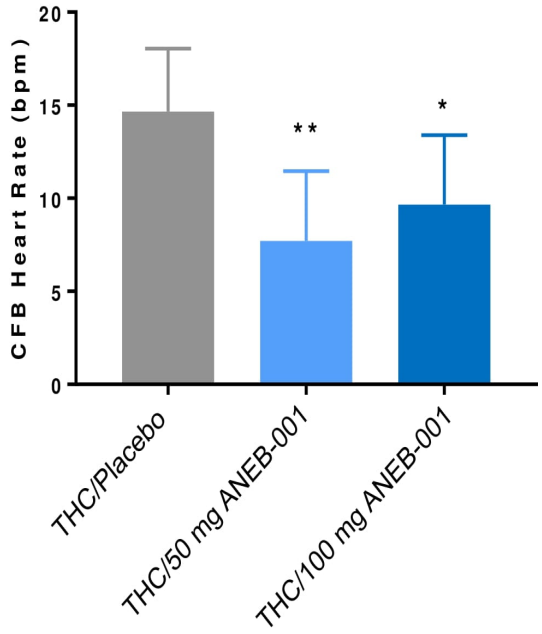
Data are mean, 95% CI

*p <0.05, unpaired t-test

ANEBULO PHARMACEUTICALS

ANEB-001 Reduced THC-Induced Heart Rate Increase

Maximum Change from Baseline in Heart Rate



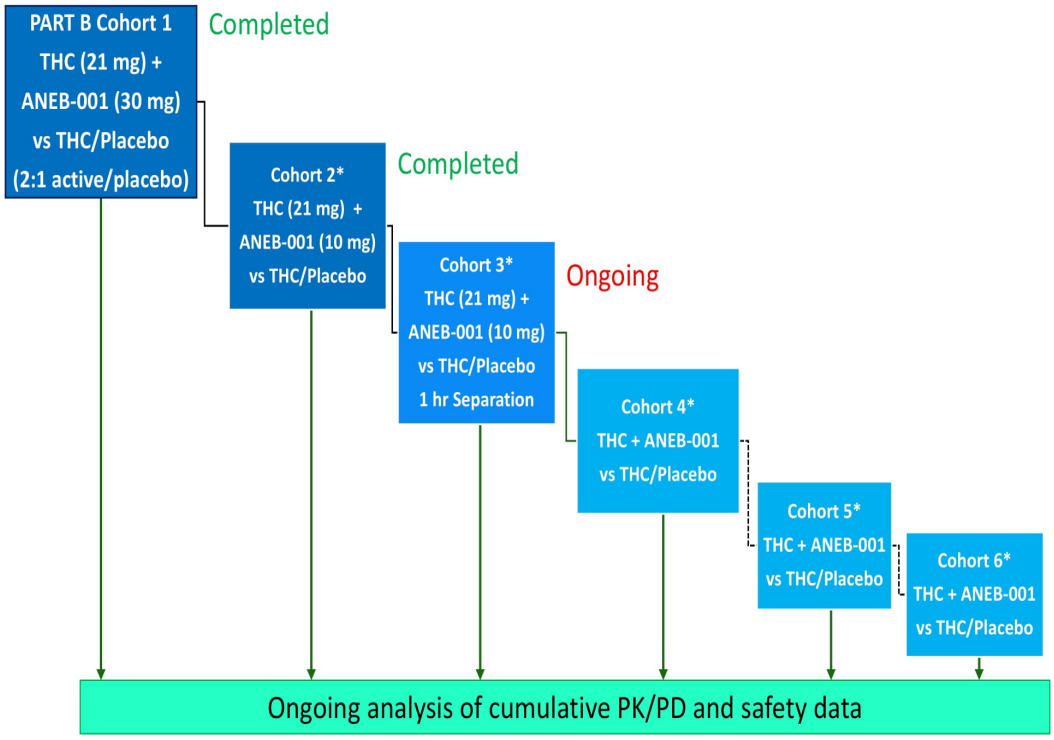
- Administration of 10.5 mg oral THC alone produced an increase in heart rate
- ANEB-001 showed a significant reduction in the maximum change from baseline for heart rate
- The 50 mg dose of ANEB-001 produced a similar effect to the 100 mg dose

Data are mean, 95% CI

*p <0.05, unpaired t-test; **p <0.01, unpaired t-test

ANEBULO PHARMACEUTICALS

Phase 2 (Part B) Adaptive Study Design



*Iterative decisions on dose levels in subsequent cohorts driven by emerging data. Cohorts of up to 15 (2:1 active/placebo)

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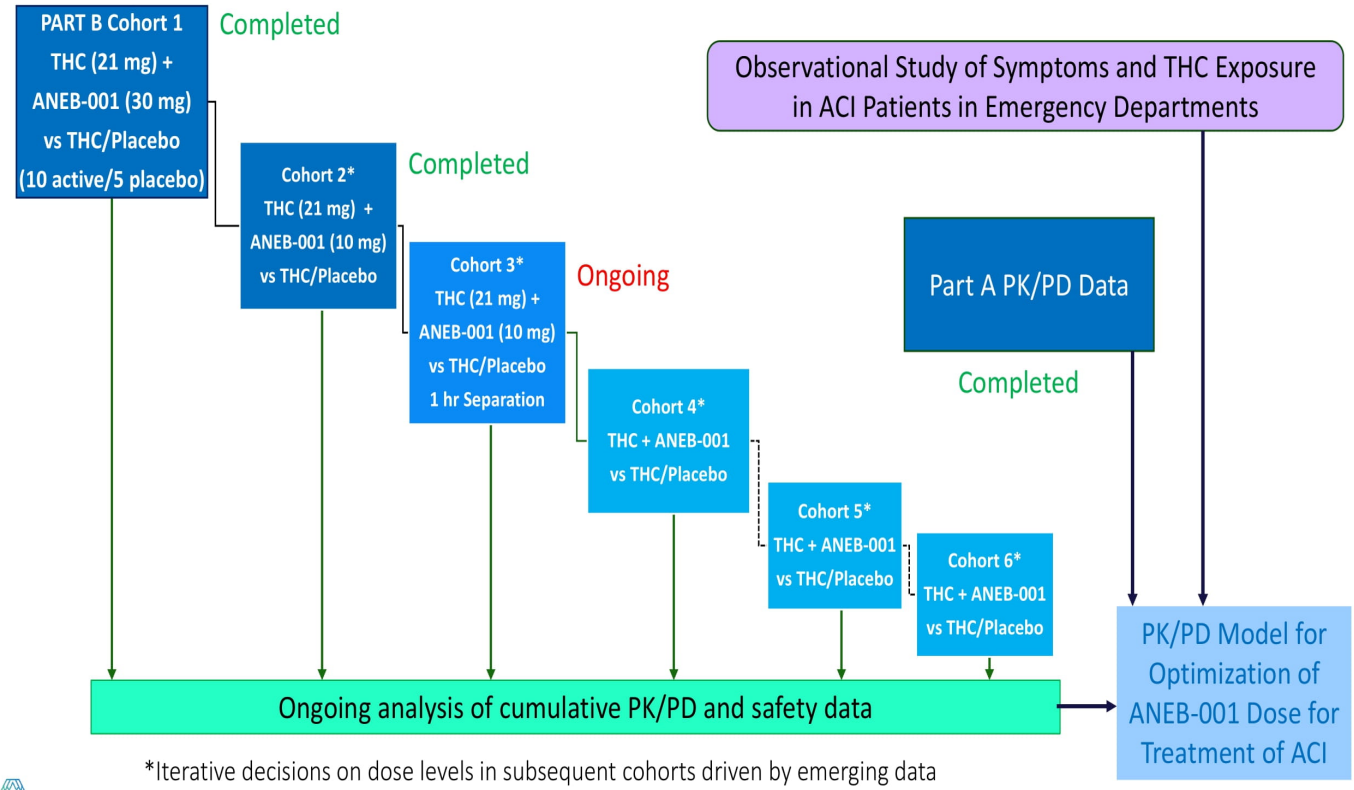
Phase 2 and Observational Study Data for PK/PD Modeling



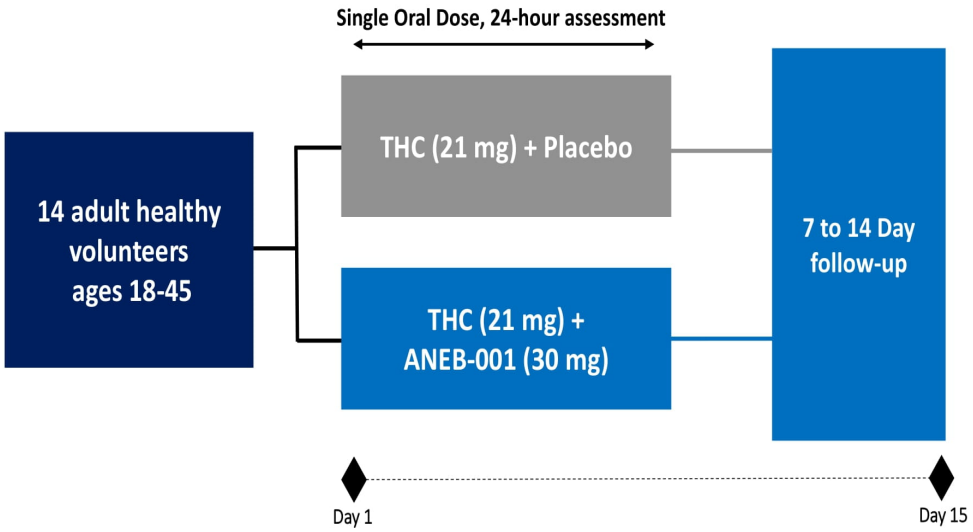
*Iterative decisions on dose levels in subsequent cohorts driven by emerging data

ANEBULO PHARMACEUTICALS

Part B Cohort 1 – Study Design

Primary Objective: To investigate the ability of ANEB-001 to inhibit the psychotropic effects of Δ9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

Randomized, double-blind, placebo-controlled study



Endpoints:

Primary: inhibition of central nervous system effects of THC

- Visual analog scale "Feeling High"
- Visual analog scale "Alertness"
- Body sway
- Heart rate

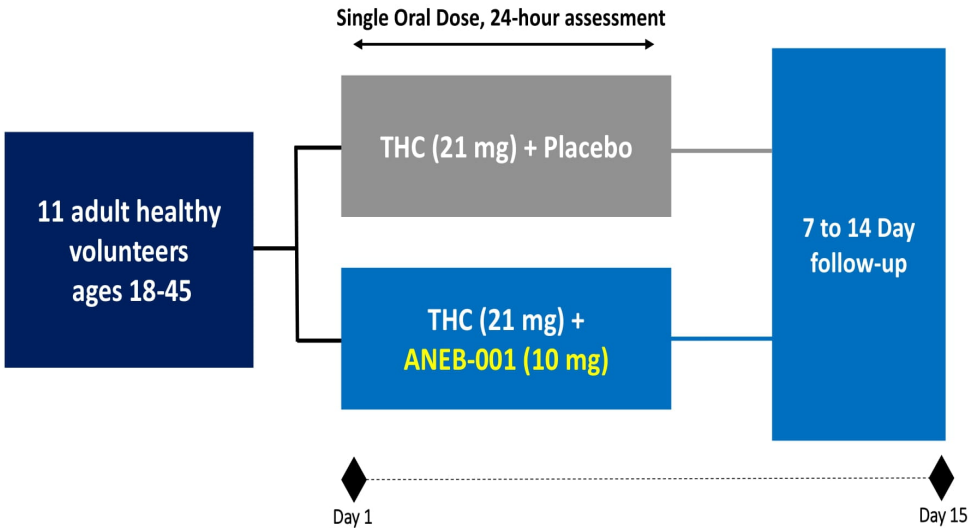
Secondary: additional efficacy metrics, safety/tolerability, PK, PK/PD correlations

ANEBULO PHARMACEUTICALS

Part B Cohort 2 – Study Design

Primary Objective: To investigate the ability of ANEB-001 to inhibit the psychotropic effects of Δ9-Tetrahydrocannabinol (THC), the main psychoactive constituent of cannabis.

Randomized, double-blind, placebo-controlled study



Endpoints:

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, PK, PK/PD correlations

ANEBULO PHARMACEUTICALS

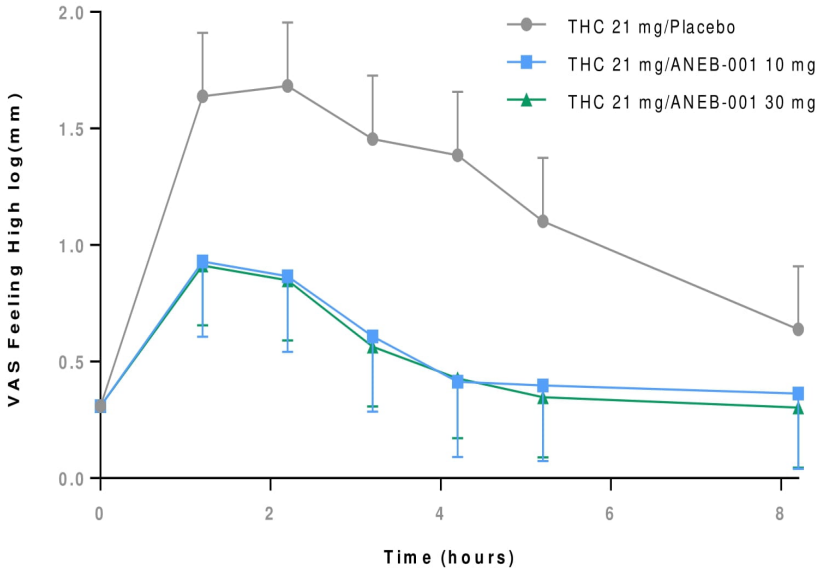
Part B Cohorts 1 and 2 - Interim Data Update

Available Interim data:

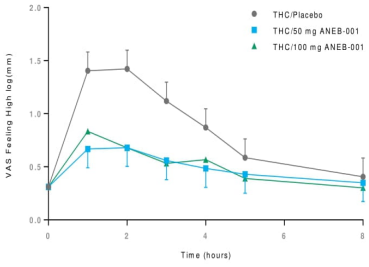
- Blinded safety data
- Primary PD data (VAS feeling high, VAS alertness, body sway, heart rate) by treatment group with statistical analysis
- Placebo data for the first two cohorts (21 mg THC) were pooled for the analysis
- PK data for ANEB-001 and THC in plasma
- PD analysis of relationship between THC dose and maximum VAS feeling high
- Impact of ANEB-001 on the THC dose response for VAS feeling high

Part B Cohort 1 & 2 Preliminary Data - Effect on Feeling High

Time Course of VAS Feeling High



- Oral administration of 21 mg THC alone produced a substantial increase in the VAS feeling high score
- Coadministration of THC with 10 mg or 30 mg ANEB-001 led to a substantial reduction in feeling high versus THC alone ($p < 0.001$)
- Effect of 10 mg ANEB-001 equivalent to 30 mg dose and comparable to the prior 50/100 mg data despite doubling the THC dose

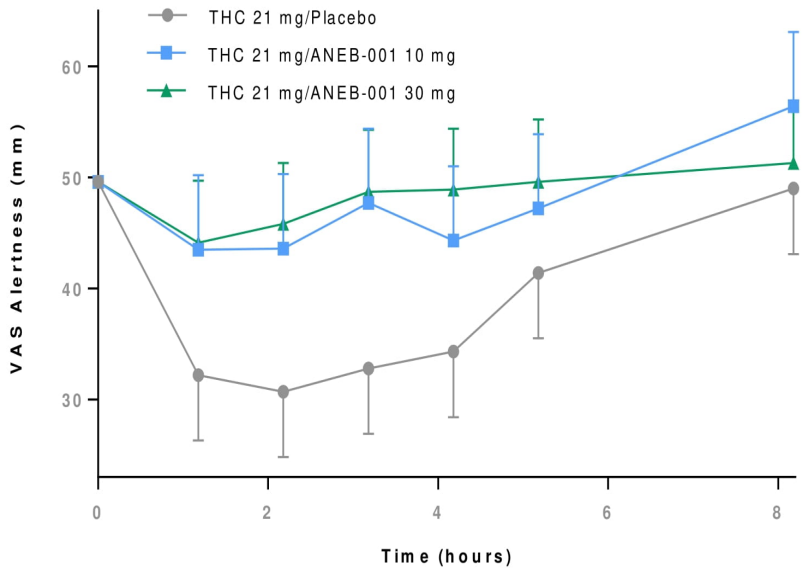


ANEBULO PHARMACEUTICALS

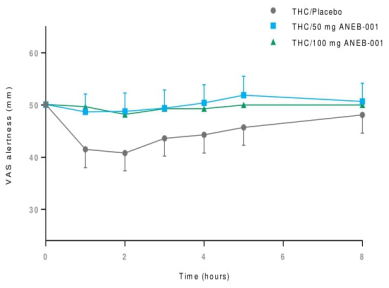
Data are least squares mean, 95% CI

Part B Cohort 1 & 2 Preliminary Data - Effect on Alertness

Time Course of VAS Alertness



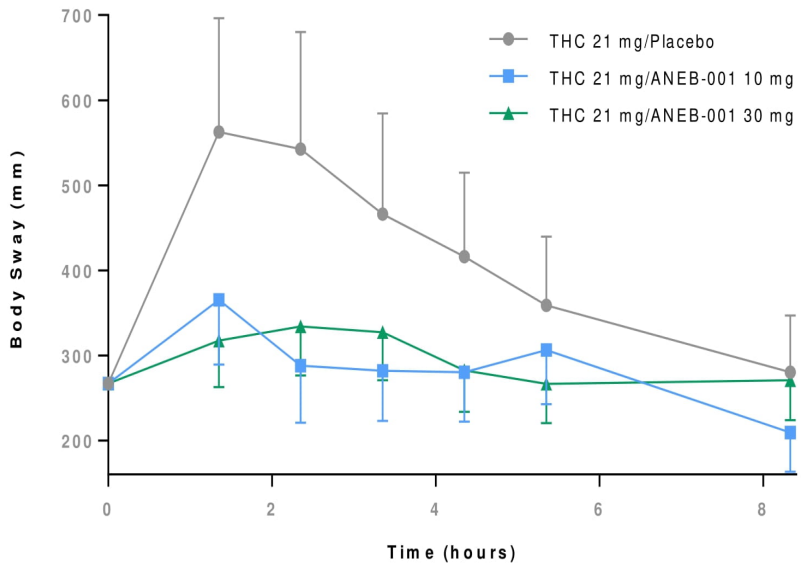
- Oral administration of 21 mg THC alone produced a substantial decrease in VAS alertness score
- Coadministration of THC with 10 mg or 30 mg ANEB-001 blocked the change compared to THC alone ($p < 0.01$)
- Effect of 10 mg ANEB-001 equivalent to 30 mg dose and comparable to the prior 50/100 mg data despite doubling the THC dose



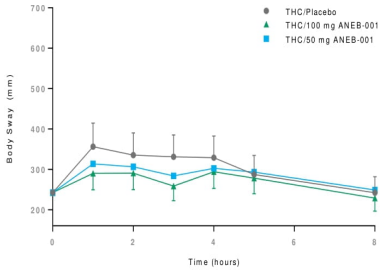
Data are least squares mean, 95% CI

Part B Cohort 1 & 2 Preliminary Data - Effect on Body Sway

Time Course of Body Sway



- Administration of 21 mg THC alone produced an increase in body sway, and 2 subjects were too dizzy to perform the test
- Coadministration of THC with ANEB-001 showed a significant reduction in mean body sway ($p < 0.01$)
- Effect of 10 mg ANEB-001 equivalent to 30 mg dose and comparable to the prior 50/100 mg data despite doubling the THC dose

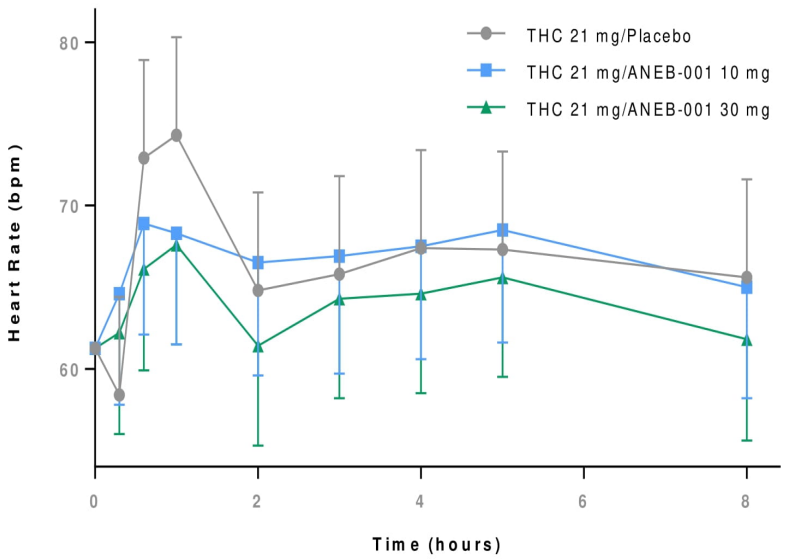


ANEBULO PHARMACEUTICALS

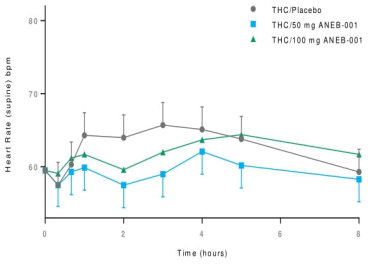
Data are least squares mean, 95% CI

Part B Cohort 1 & 2 Preliminary Data - Effect on Heart Rate

Time Course of Heart Rate



- Administration of 21 mg THC alone had only a minor effect on heart rate
- Coadministration of THC with ANEB-001 showed a trend towards normalization of heart rate
- The 10 mg dose of ANEB-001 was as effective as the 30 mg dose

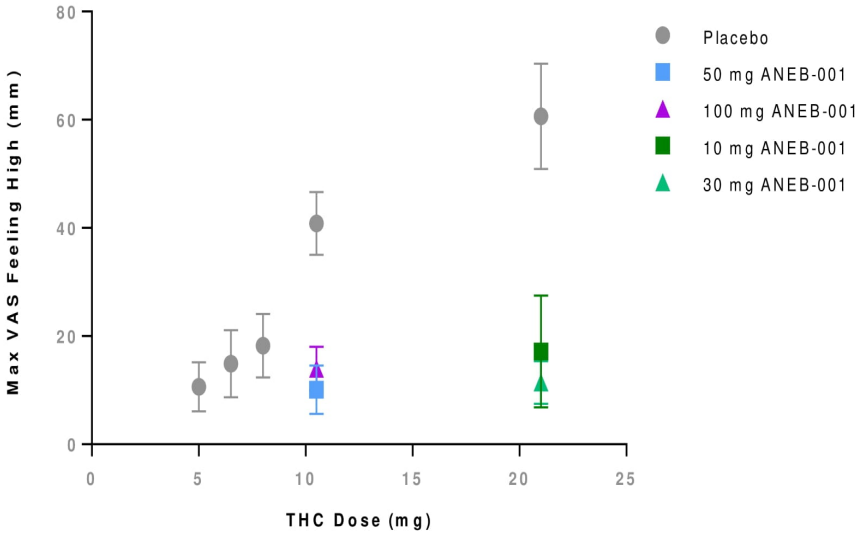


ANEBULO PHARMACEUTICALS

Data are least squares mean, 95% CI

Effect of THC Dose on Feeling High

Maximum VAS Feeling High Score vs. THC Dose



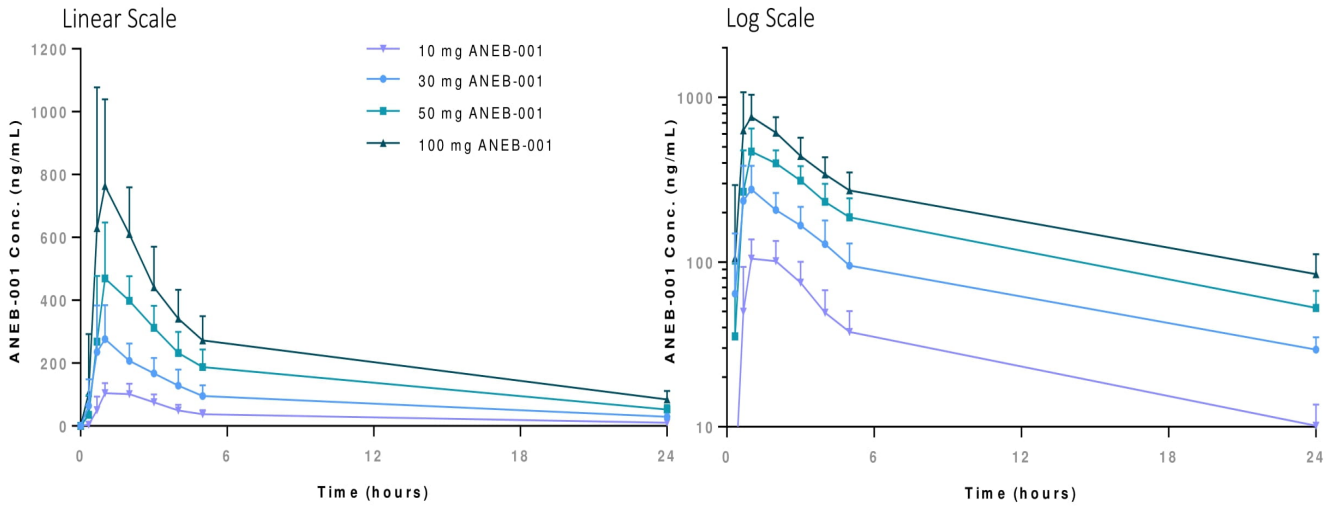
Values are mean (SEM)

- Plot compares PD data from THC Challenge studies: Part A, Part B Cohorts 1 and 2, and published data for THC challenge at lower doses[1]
- Clear dose response for THC/placebo – increased feeling high with increasing THC dose
- 100% of subjects given 21 mg THC and placebo were high (>20 mm VAS score) vs. only one subject in each of the 10 mg and 30 mg ANEB-001 groups
- All ANEB-001 doses effective in reducing the THC effect on feeling high
- The 10 mg ANEB-001 was as effective as higher doses in reducing VAS feeling high despite the higher 21 mg THC dose
- Confirms potent effect of ANEB-001 on CB1 receptor

[1]Source: Klumpers LK et al, Br J Clin Pharmacol 2012 Jul;74(1):42-53.

Phase 2 Part A and Part B Interim Data: PK of ANEB-001

Pharmacokinetics of ANEB-001 in Plasma of Subjects Challenged with THC[1]

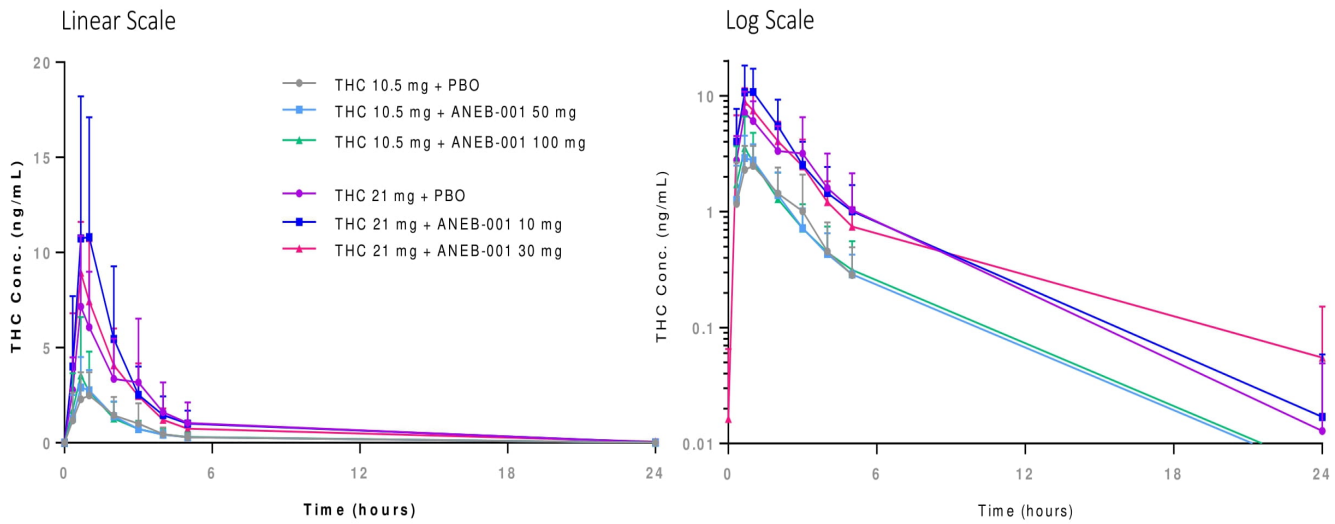


- Rapidly absorbed (T_{max} = 1 hour)
- Dose-related exposure to ANEB-001
- Long half-life supports once daily dosing

[1]Data are Mean (SD)

Phase 2 Part A and Part B Interim Data: PK of THC in Plasma

Pharmacokinetics of THC in Plasma of Healthy Subjects Challenged with THC[1]



- Oral THC tablets provided dose-related THC exposure
- Consistent with published exposure data for THC tablets

[1]Data are Mean (SD)

Part B Cohorts 1 and 2 - Interim Data Conclusions

THC Dose Effect:	21 mg THC produced stronger intoxication effects compared to 10.5 mg in Part A
VAS Feeling High:	ANEB-001 (10 or 30 mg) produced a sustained reduction in feeling high ($p < 0.001$)
VAS Alertness:	ANEB-001 (10 or 30 mg) produced a sustained improvement in alertness ($p < 0.01$)
Body Sway:	ANEB-001 (10 or 30 mg) produced a significant improvement in body sway $p < 0.01$)
Heart Rate:	THC effect on heart rate was small – trend towards reduction by ANEB-001
Dose response:	10 mg ANEB-001 was as effective as higher doses despite the higher THC dose, confirming potency of ANEB-001 as an antagonist of CB1-mediated effects of THC
Preliminary Safety:	**Data Still Blinded:** All adverse events in cohort 1 were mild and transient except two cases of moderate dizziness likely attributable to THC. All adverse events in cohort 2 were mild and transient.

Part B Cohort 3 - Protocol Amended and Dosing Initiated

- Protocol amended to allow staggered dosing and add additional time points/subjective measures
- Cohort 3: staggered single oral doses of 21 mg oral THC and 10 mg ANEB-001 or placebo
- THC will be administered 1 hour before ANEB-001/placebo
- Study endpoints include all of those assessed in Part A
- New “post-THC baseline” assessments added prior to administration of ANEB-001
- Allows for evaluation of within subject changes
- New “drug effect” VAS scores added
- Protocol details will be posted in the clinicaltrials.gov record
- Protocol includes 6 cohorts in total for Part B

Observational Study in ACI Patients

Study Title:	Multi-center observational study of plasma concentrations of THC and its metabolites in subjects visiting emergency departments for acute cannabinoid intoxication
Primary Objective:	To determine plasma concentrations of THC and its metabolites, 11-OH-THC and THC-COOH (and/or other cannabinoids), in plasma of subjects who visit the ED due to ACI
Study Design:	Subjects presenting to Emergency Departments with ACI based on a subset of DSM-V diagnostic criteria. Collection of THC PK, signs and symptoms, interventions, disposition, and selected subjective PD assessments at entry and discharge. Targeting 10 to 20 sites and approx. 120 subjects. Plasma sample at entry and possible additional time points.
Est. completion:	Approx. 12 months total but data will be used as generated for PK/PD modeling during the study
Clinicaltrials.gov:	Registration planned

Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling

Objective:	To develop a PK/PD model to predict the optimal ANEB-001 dose for treating ACI
Components:	• Historical data for THC PK and PD outcomes in healthy subjects • New PK/PD data for THC and ANEB-001 from Anebulo Phase 2 challenge study • New data for THC PK/PD in ACI patients from Anebulo observational study
FDA involvement:	• Discussed with FDA/MIDD (Model-Informed Drug Development) Group • Initial meeting with MIDD completed in June 2022 • Next meeting scheduled for November 2022

ANEB-001 Potential Regulatory Path

- Previous Pre-IND Meeting held in December 2021
- Discussions ongoing with FDA's Model-Informed Drug Development team
- First Proposed US Study: Multi-center Observational study in ACI subjects
- Intended to support PK/PD model development and dose selection for ACI
- Study initiation expected in 4Q 2022
- Next MIDD meeting scheduled for November 2022
- Potential End of Phase 2A meeting following completion of Part B with ongoing PK/PD modeling
- Potential for first ANEB-001 study in US to be a registrational study subject to FDA agreement

ANEB-001: Additional Activities – CMC and Nonclinical

CMC Activities:

- Emerging Phase 2 data supportive of a lower ANEB-001 dose than originally projected
- Drug substance manufacturing already ongoing at “commercial” scale
- Drug product manufacturing on track to support clinical and commercial use

Nonclinical Activities:

- IND enabling studies previously completed including up to 4 weeks tox in 2 species
- Intended as a single dose product – we do not anticipate chronic dosing for ANEB-001
- Remaining nonclinical studies to support potential Phase 3 clinical studies are planned

ANEB-001 Parenteral Product Development Program

Status:

- Potential for use in ACI subjects unable to swallow oral capsules
- Preferred route of administration for pediatric subjects
- Targeting single dose IV or IM injection to be administered in Emergency Department
- Multiple novel prototype parenteral formulations currently being evaluated

Next Steps:

- Initial evaluation in nonclinical PK models
- Selection of a lead formulation for clinical development
- GMP scale up and initiation of IND enabling studies
- Scope of required studies depends on PK comparability versus existing safety data
- First in human dosing of parenteral formulation would be a Phase 1 study
- New opportunities for additional IP coverage

ANEB-001 Clinical Development for ACI - Summary

Phase 2 Part A New Data: Dose related exposure, reductions in body sway/heart rate

Ongoing Phase 2 Part B: 2 cohorts completed – 10 mg and 30 mg doses reduced THC-related effects despite a higher THC dose, appears safe and well tolerated

Plans for Completion of Part B: Cohort 3 ongoing using staggered dosing – 3 more cohorts currently planned for PK/PD modeling

Regulatory Update: Next FDA/MIDD meeting in November

Planned First US Clinical Study: Observational study in ACI patients

Path to Potential Approval: To be finalized after Phase 2 study is completed

Parenteral Product: Prototype formulations in development for preclinical testing

Q&A Session

Concluding Remarks

Simon Allen, Chief Executive Officer

Development plan

H2 CY22
Readout

Proof of-Concept

- Phase 2 study at single site in Netherlands
- Up to 150 healthy volunteers
- THC + doses of ANEB-001 or placebo

Pivotal Program

- FDA pre-IND meeting provided valuable guidance on U.S. regulatory path

New Drug Application

- Exploration of strategic options for rights outside of the U.S.

Intellectual Property Portfolio

- Method of use patent
  - Issued October 2021
  - Protection through 2040
- Strategy to enhance IP portfolio

Lifecycle management

In summary

ANEBULO PHARMACEUTICALS

Addressing unmet medical need in a large and growing market, with acute cannabinoid intoxication becoming an increasingly widespread health issue

ANEB-001 has a well-understood mechanism of action as a CB1 antagonist

Phase 2 proof-of-concept study continues (Part A topline data released July 5, 2022; Part B initiated in Q3 2022)

Capital-efficient business model with $14.5M cash (06/30/22)

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