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): July 5, 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, Texas	**78734**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (512) 598-0931

N/A
(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.

On July 5, 2022, Anebulo Pharmaceuticals, Inc. (the "Company") updated its corporate slide presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

On July 5, 2022, the Company issued a press release titled "Anebulo Pharmaceuticals Announces Positive Topline CNS Data for ANEB-001 from Part A of Ongoing Phase 2 Clinical Trial for Acute Cannabinoid Intoxication." A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibits 99.1 and 99.2) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Slide Presentation, dated July 5, 2022
99.2	Press Release, dated July 5, 2022
104	Cover Page 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.

By: */s/ Rex Merchant*
Rex Merchant
Chief Financial Officer

Dated: July 5, 2022

Forward Looking Statements

Cautionary Note Regarding Forward-Looking Statements

This presentation contains 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. These forward-looking statements, along with terms such as "anticipate," "expect," "intend," "may," "will," "should" and other comparable terms, involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of Anebulo Pharmaceuticals, Inc. (the "Company") and members of its management, as well as the assumptions on which such statements are based. These forward-looking statements include, but are not limited to, those regarding the potential benefits to ANEB-001, including as a result of the Company's ongoing IP strategy, ease of manufacturing small molecules and its simple mechanism of action; the Company's belief that ANEB-001's simple mechanisms reduce the risk of clinical failure; the Company's expectations that cannabis associated ED visits will continue to rise; the possibility that individuals intoxicated with cannabinoids may require expensive follow-on interventions for neuropsychiatric complications; the Company's goals to provide physicians with an effective and fast-acting treatment for the symptoms of ACI; the Company's development plans for ANEB-001 including the design, progress and expected timing of the Company's clinical studies and the Company's intention to submit an Investigational New Drug application ("IND") for ANEB-001 to the U.S. Food and Drug Administration ("FDA") and the expected timing thereof; the Company's commercialization plans for ANEB-001, if approved, including plans to expand the Company's IP position and explore different routes of administration for ANEB-001 and Animal Health / Canine ACI. Prospective investors 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: there is no guarantee that the Company's planned IND for ANEB-001 will be cleared by the FDA; initial 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 the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company's business, commercialization and product development plans caused by or associated with COVID-19 or geopolitical issues; and those described in the Company's most recent annual report on Form 10-K and in other periodic reports filed with the SEC, and that actual results may differ materially from those contemplated by such forward-looking statements. Except as required by federal securities law, the Company undertakes no obligation to update or revise forward-looking statements to reflect changed conditions. Recipients are cautioned not to place undue reliance on these statements and that the foregoing may not contain all of the forward-looking statements made in this presentation.

Market & Industry Data

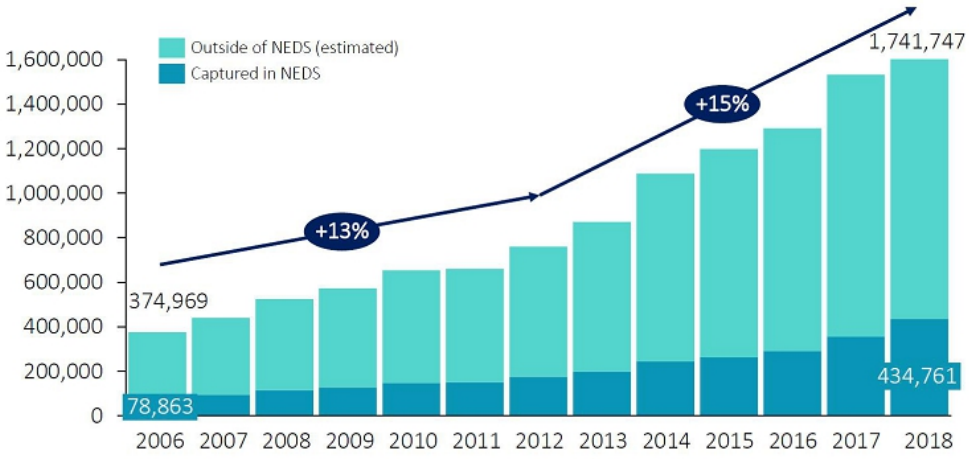
This presentation includes market and industry data and forecasts that the Company has developed from independent research reports, publicly available information, various industry publications, other published industry sources or the Company's internal data and estimates. Independent research reports, 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 the Company believes that the publications and reports are reliable, the Company 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. The Company'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 the Company believes that such information is reliable, the Company has not had such information verified by any independent sources.

ANEBULO: Addressing Acute Cannabinoid Toxicity

- US based clinical stage biotech focused on ACI and substance abuse disorders
- Focused on developing the first FDA approved therapy for ACI
- ANEB-001 benefits from:
  - ✓ Positive Phase 2 Proof-of-Concept Data
  - ✓ Anebulo's issued patent and ongoing IP strategy
  - ✓ Clear and well understood mechanism of action
  - ✓ Prior big pharma investment
  - ✓ Easy to manufacture small molecule

Cannabis Associated Emergency Department Visits Increase

Annual cannabis associated ED visits in the U.S., 2006-2018



US Emergency Department admissions for cannabis intoxication increase at 15% after "legalization" (2012)

We believe

over 1.7M

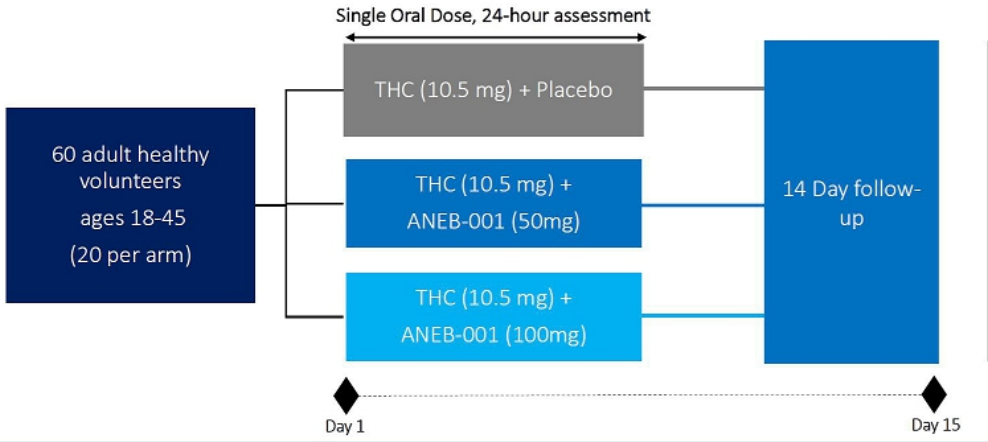
ED visits in 2018 were associated with cannabis

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

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:

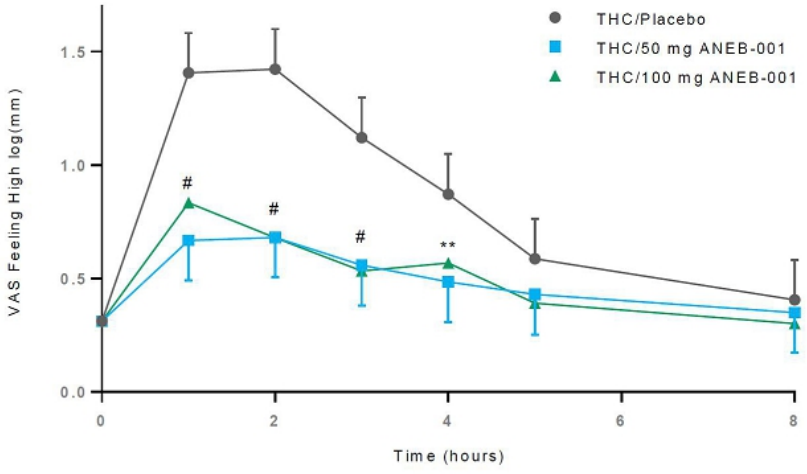
Primary: inhibition of central nervous system effects of THC

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

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

ANEB-001: Produced Sustained Reduction of Feeling High

Time Course of VAS Feeling High



- Administration of oral THC alone produced a substantial increase in the VAS feeling high score
- Coadministration of THC with ANEB-001 led to a highly significant 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

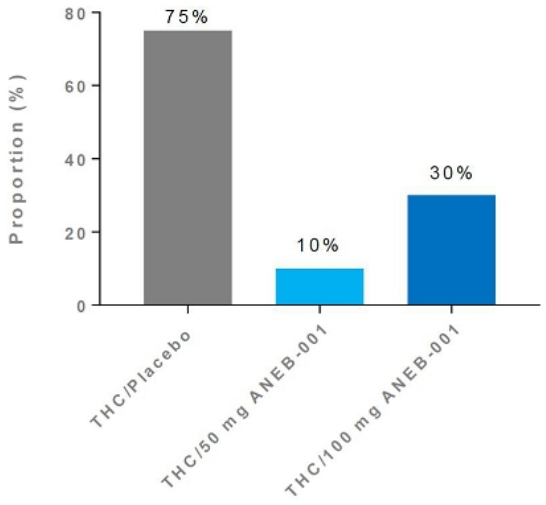
Data are least squares mean, 95% CI

# $p < 0.0001$ for both dose levels

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

ANEB-001: Reduced the Proportion of Subjects Feeling High

Proportion of Subjects Reporting Feeling High*



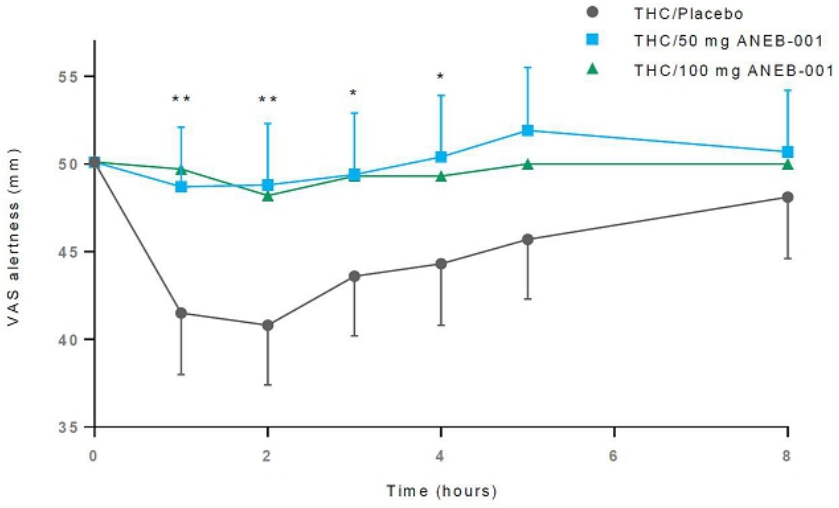
- 75% of subjects dosed with THC alone reported feeling high
- Only 10% of subjects given THC with 50 mg ANEB-001 and 30% of subjects given THC with 100 mg ANEB-001 reported feeling high
- Coadministration of THC with ANEB-001 led to a highly significant decrease in the proportion of subjects reporting feeling high (overall p <0.001)
- The 50 mg ANEB-001 was as effective as the 100 mg dose

*based on a score of at least 20/100 on the VAS feeling high scale

ANEBULO

ANEB-001: Produced Sustained Improvement in Alertness

Time Course of VAS Alertness



- Administration of oral THC alone produced a substantial reduction in alertness
- ANEB-001 significantly inhibited the reduction in alertness compared to administration of THC alone (overall p <0.01)
- The effect of ANEB-001 on improving alertness was sustained
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

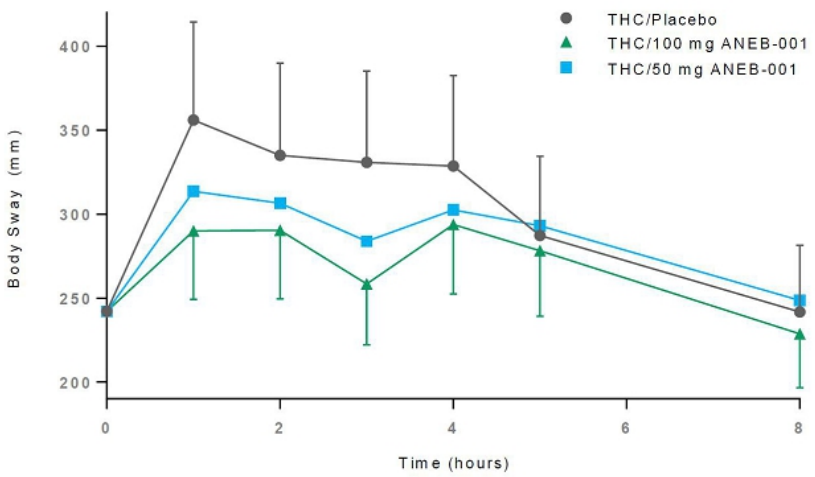
**p < 0.01 for both dose levels

*p < 0.05 for both dose levels

ANEBULO

ANEB-001: Effect on THC-Induced Body Sway

Time Course of Body Sway



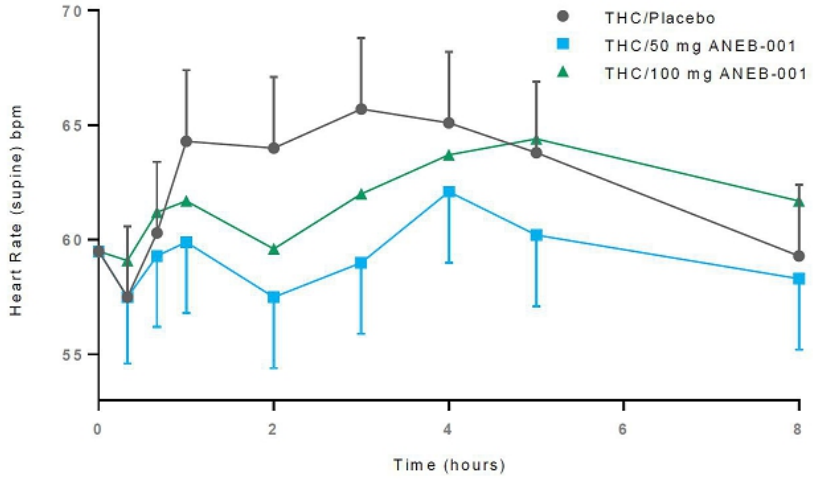
- Administration of oral THC alone produced an increase in body sway, although inter-subject variability was high
- Coadministration of THC with ANEB-001 showed a trend towards reduced body sway
- The effect of ANEB-001 on reducing body sway did not reach statistical significance overall
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

ANEBULO PHARMACEUTICALS

ANEB-001: Effect on Heart Rate

Time Course of Heart Rate



- Heart rate was measured repeatedly during the study
- Administration of 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 effect of ANEB-001 on heart rate did not reach statistical significance overall
- The 50 mg dose of ANEB-001 was as effective as the 100 mg dose

Data are least squares mean, 95% CI

ANEBULO PHARMACEUTICALS

ANEB-001: Topline Data for Part A of Phase 2 POC Study

Primary Outcomes:

- VAS Feeling High: Highly significant and sustained improvement ANEB-001 ($p < 0.0001$) at both dose levels
- Proportion of Subjects Reporting Feeling High on VAS: 75% for THC/placebo versus 10% on 50 mg ANEB-001 and 30% on 100 mg ANEB-001 ($p < 0.01$)
- VAS Alertness: Significant improvement in alertness for both 50 mg and 100 mg ANEB-001 ($p < 0.01$)
- Body Sway: THC effect on body sway was small; trend to improvement for ANEB-001, although not statistically significant
- Heart Rate: THC effect on heart rate was small; ANEB-001 showed trend to normalization of heart rate, although not statistically significant
- Dose response: 50 mg and 100 mg dose of ANEB-001 had similar activity, supports use of a lower dose in Part B and a higher dose of THC

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ANEB-001: Topline Data for Part A of Phase 2 POC Study

Secondary Outcomes:

- VAS external perception: Significant improvement at both dose levels ($p < 0.01$)
- VAS nausea: No significant difference overall between treatment groups
- Other secondary VAS scores: No significant differences between treatment groups
- Preliminary Safety: All adverse events were mild and transient except in the case of one subject in the 50 mg ANEB-001 group who experienced moderate nausea and vomiting

ANEBULO

ANEB-001: Next Steps

Development

- Awaiting final safety and PK data from Part A
- Completion of Part A data analysis and PK/PD correlations
- Initiation of Part B of the Phase 2 study to explore a lower ANEB-001 dose and a higher THC challenge dose
- 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
- Submit an IND by the end 2022

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

Anebulo Pharmaceuticals, Inc.

Scott Anderson
Head of Investor Relations
scott@anebulo.com

Rex Merchant
CFO
rex@anebulo.com

Exhibit 99.2

Anebulo Pharmaceuticals Announces Positive Topline Data for ANEB-001 from a Phase 2 Clinical Trial for Acute Cannabinoid Intoxication

- **Study Met Primary Endpoint VAS Feeling High ($p < 0.0001$)**
- **Statistically Significant and Sustained Reductions in Key THC-Related CNS Symptoms**
- **Conference Call 8:30am Eastern Time Today**

AUSTIN, Texas (July 5, 2022) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance abuse disorders (the "Company" or "Anebulo"), today announced positive topline data from Part A of an ongoing Phase 2 clinical trial evaluating the potential of ANEB-001 to treat ACI. Part A was a 60 subject randomized, double-blind, placebo-controlled trial designed to evaluate the effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with delta-9-tetrahydrocannabinol, better known as THC, the primary psychoactive constituent of cannabis. These data demonstrated a highly statistically significant reduction in key symptoms of ACI, with only 10% of subjects in the 50 mg ANEB-001 group and 30% in the 100 mg group reporting feeling high compared to 75% of subjects in the placebo group ($p < 0.001$). ANEB-001 was well tolerated in these healthy volunteers. Preliminary safety information showed all adverse events were mild and transient, except in the case of one subject in the 50 mg ANEB-001 group who experienced moderate nausea and vomiting.

"We believe this proof-of-concept trial demonstrates ANEB-001's potential to reverse the symptoms of ACI for many of the five thousand cannabinoid intoxicated individuals visiting our emergency departments in the United States on a daily basis," said Simon Allen, Chief Executive Officer of Anebulo. "We believe marijuana legalization and greater consumer access to cheaper and higher potency THC products will continue to increase the incidence and severity of emergency department visits related to cannabinoid intoxication. With no FDA approved therapy, individuals intoxicated with cannabinoids have few treatment options and may require expensive follow-on interventions for neuropsychiatric complications such as anxiety and acute psychosis. ANEB-001 has the potential to mitigate these unfortunate circumstances and reduce their burden on individuals, society, and our healthcare system."

The study was conducted at the Centre for Human Drug Research (CHDR) in the Netherlands and enrolled 60 healthy adult occasional cannabis users randomized to three treatment arms of 20 subjects per arm. All subjects were challenged with a single oral dose of 10.5 mg THC and then treated with single oral doses of 50 mg ANEB-001, 100 mg ANEB-001, or placebo. Subjects were monitored for 24 hours to assess safety, tolerability, and pharmacokinetics, and repeatedly tested to determine potential effects on endpoints related to ACI symptoms. The tests also included a series of validated measures of subjective CNS symptoms using visual analog scale (VAS) assessments, as well as objective measures of intoxication. Subjects challenged with THC and treated with placebo showed substantial CNS effects including feeling high, decreased alertness, increased body sway, and increased heart rate. Compared to placebo, treatment of subjects with ANEB-001 led to a significant, robust, and sustained reduction in the VAS feeling high score ($p < 0.0001$ at both dose levels) and improvement in the VAS alertness scale ($p < 0.01$). In addition, the proportion of subjects reporting feeling high on the VAS was significantly reduced by ANEB-001 ($p < 0.001$). Although THC-induced effects on body sway and heart rate in this study were small, there was also a trend towards statistical improvement of these parameters with ANEB-001 treatment compared to placebo. The 50 mg and 100 mg doses had similar results, suggesting that lower doses should be explored. Pharmacokinetic data are pending and additional analyses of Part A data, including pharmacokinetic/pharmacodynamic (PK/PD) correlations, are planned.

"The number of individuals with cannabinoid related intoxication visiting our emergency departments is clearly on the rise," said Dr. Andrew Monte M.D., Ph.D., Professor of Emergency Medicine & Medical Toxicology, University of Colorado Denver-Anschutz Medical Center. "Patients are coming from multiple settings including first-time users taking small doses of THC, adults and children inadvertently ingesting powerful THC gummies, and regular users unintentionally overdosing on new and more powerful THC products. Introducing an effective cannabinoid antidote into our treatment options would represent a significant improvement in how we can manage these patients"

Based on the encouraging data from Part A, the Company plans to initiate Part B of the study at CHDR by the end of third quarter 2022 to evaluate lower doses of ANEB-001. Anebulo is currently collaborating with the Model-Informed Drug Development (MIDD) group at FDA to develop a PK/PD model that will potentially allow prediction of 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. Submission of an Investigational New Drug application (IND) for ANEB-001 to initiate U.S. trials is anticipated by the end of 2022.

Conference Call and Webcast

Anebulo will host a conference call and webcast today, July 5, 2022, at 8:30 am Eastern Time to discuss topline data from the ANEB-001 Phase 2 Part A Proof-of-Concept clinical trial. To access the audio webcast with slides, please visit the "Events & Presentations" page in the Investors & Media section of the Company's website at https://ir.anebulo.com/company-information/presentations. The call can also be accessed by dialing (877) 407-8815 (domestic) or +1 (201) 689-8025 (international) with conference ID 13731361.

The live audio webcast with slides can also be accessed at the following location:https://ir.anebulo.com/company-information/presentations
For those unable to participate in the conference call or webcast, a replay will be available on the Company's website.

About Visual Analogue Scale (VAS)

VAS is a tool used to help rate the intensity of certain sensations and feelings, such as feeling high. The visual analog scale is typically a straight line with one end meaning not high and the other end meaning extremely high. A patient marks a point on the line that matches how high they feel.

About Acute Cannabinoid Intoxication (ACI)

Symptoms of ACI can include increased somnolence, impaired cognition and perception, disorientation, anxiety, and acute psychosis. According to DSM-5, a diagnosis of cannabinoid intoxication should include recent history of cannabinoid use, clinically considerable behavioral or psychological changes, such as euphoria, impaired judgment and motor skills, which have taken place since cannabinoid exposure.

About CHDR

The Centre for Human Drug Research (CHDR) is an independent institute that specializes in cutting-edge early-stage clinical drug research. Combining innovative methods and technologies, state-of-the-art facilities, and talented, motivated researchers helps CHDR maximize their clients' success. In addition, CHDR places the highest priority on their subjects' comfort and safety, and they play an active role in helping educate the medical and clinical research communities.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse disorder. Its lead product candidate, ANEB-001, is currently in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) to evaluate its utility in reversing the negative effects of acute cannabinoid intoxication within one hour of administration. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

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