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): **March 3, 2020**

ZYNERBA PHARMACEUTICALS, INC.

(Exact Name of Issuer as Specified in Charter)

Delaware	**001-37526**	**26-0389433**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

80 W. Lancaster Avenue, Suite 300
Devon, PA 19333
(Address of Principal Executive Offices)

(484) 581-7505
(Registrant's Telephone Number, Including Area Code)

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	ZYNE	The NASDAQ Global Market

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 8.01 Other Events

On March 3, 2020 Zynerba Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it is presenting a two posters at the American Society for Experimental Neurotherapeutics 2020 Meeting in Bethesda, MD (ASENT 2020 Meeting). The posters relating to the health burden and diagnostic challenges of Fragile X syndrome (FXS) are entitled "Post Hoc Analysis - An Open-Label Study of Transdermal Cannabidiol (ZYN002) for the Treatment of Fragile X Syndrome in Children and Adolescents: Estimating Health State Utility Scores" and "Fragile X Syndrome Diagnosis and Patient Journey: The Caregiver's Perspective".

On March 3, 2020, the Company issued a second press release announcing that is presenting a third poster at the ASENT 2020 Meeting describing the baseline characteristics of the pediatric and adolescent patients in the Company's Phase 2 BRIGHT trial entitled "Phase 2 BRIGHT (An Exploratory Open-La**b**el Tole**r**ab**i**lity and Efficacy Study of ZYN002 Administered as a Transdermal **G**el to C**h**ildren and Adolescen**t**s with Autism Spectrum Disorder) Trial: Baseline Characteristics."

Copies of these press releases are attached hereto as Exhibits 99.1 and 99.2 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

The following exhibits are being filed herewith:

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated March 3, 2020
99.2	Press Release, dated March 3, 2020

SIGNATURE

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.

Date: March 3, 2020

ZYNERBA PHARMACEUTICALS, INC.

By: /s/ Suzanne Hanlon
Name: Suzanne Hanlon
Title: Secretary, Vice President and General Counsel

Zynerba Pharmaceuticals Presents Health State Utility Index Data on Severity of Fragile X Syndrome (FXS) and Diagnostic Challenges Faced by Caregivers

- Data Presented at the American Society for Experimental Neurotherapeutics (ASENT) 2020 Meeting -

- Health State Utility Index Data Estimate the Significant Health Burden of FXS, and Suggest the Potential Benefit of Treatment with Zygel™ -

- Caregiver's Perspective on Protracted Journey to Diagnosis, Current Standard of Care and Comorbid Conditions Described -

DEVON, Pa., March 3, 2020 – Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, is presenting two posters this week on the health burden and diagnostic challenges of Fragile X syndrome (FXS). These data are being presented at the American Society for Experimental Neurotherapeutics (ASENT) 2020 Meeting, which is being held In Bethesda, MD on March 2nd through March 5th, 2020.

The first poster presents health state utility indices that estimate the severity of pediatric disorders including FXS, and the potential benefit of Zygel (CBD transdermal gel; ZYN002) in children and adolescents with FXS. Joseph M. Palumbo, MD, FAPA, MACPsych, Chief Medical Officer of Zynerba, will also present these data during the ASENT Pipeline Data Blitz on March 4. The second poster speaks to the initial family experience in FXS, expanding upon the existing knowledge of patient presentation, diagnosis and understanding of FXS; the protracted journey to diagnosis; and the high prevalence of comorbid conditions. A copy of the posters are available on the Zynerba corporate website at http://zynerba.com/publications/.

Post Hoc Analysis - An Open-Label Study of Transdermal Cannabidiol (ZYN002) for the Treatment of Fragile X Syndrome in Children and Adolescents: Estimating Health State Utility Scores

- *Poster number: 29*
- *Poster presentation time: Tuesday, March 3 from 5:00 to 6:00 PM and Wednesday, March 4 from 5:00 to 7:00 PM.*
- *Oral presentation time: Wednesday, March 4 from 1:00 to 3:00 PM during* the ASENT Pipeline Data Blitz session.

FXS is a rare genetic condition characterized by a range of developmental, neuropsychiatric, and behavioral symptoms. The spectrum and severity of FXS symptoms result in a high clinical, humanistic, and economic burden on patients and caregivers, including important healthcare resource utilization and associated costs. Health state utility indices (HUI) are used in clinical and economic analyses of therapies with potential impact on health-related quality of life (HRQoL) and enable comparison of HRQoL across conditions. Health state utility is measured on a 0 to 1 scale in which 0 represents death and 1 represents complete health; the lower the score, the more significant the impact of the disease to HRQoL. The Aberrant Behavior Checklist - Community Utility Index (ABC-UI) - a utility index specific to FXS - was derived from the Aberrant Behavior Checklist - Community for FXS ($ABC\text{-}C_{FXS}$) to measure the HRQoL benefit of treatments for FXS. The ABC-UI, created and subsequently published in the peer-reviewed journal *Quality of Life Research*, in 2015, established an algorithm that calculates utility index score based on $ABC\text{-}C_{FXS}$ items pertaining to the core symptom domains of FXS.

“The mean health state utility index score for FXS in this seminal analysis was calculated to be 0.57, estimating a significant disease-related impact on HRQoL in FXS which may be as robust as, or perhaps even more impactful, than that described in the published literature for other debilitating pediatric conditions in measures of HUI”, said Dr. Palumbo. “We will work to confirm our initial observations in future analyses.”

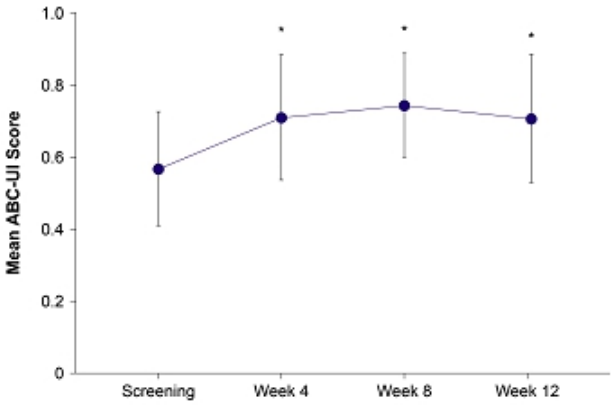
The objective of the analysis undertaken was to evaluate the potential benefit of Zygel on the ABC-UI in pediatric and adolescent patients with FXS through post hoc analysis of data from the Phase 2 open label FAB-C (Treatment of **F**ragile X Syndrome **A**nxiety and **B**ehavioral **C**hallenges with CBD) trial. Individual patient-level data from the FAB-C study were mapped to the ABC-UI algorithm to generate a utility index score for each patient.

“Fragile X syndrome is a debilitating diagnosis, and for the first time we have estimated the health state utility index scores of patients with FXS, in the context of the published HUI literature, helping to clarify the significance of this disorder,” continued Dr. Palumbo. “Further, we observed statistically significant improvements in the health state utility index scores of patients treated with Zygel in the 12-week exploratory Phase 2 FAB-C trial compared to baseline, suggesting a potential broad spectrum of benefit of the drug in the important domains of the ABC-C_{FXS} that were incorporated into the utility index.”

Improvement in ABC-UI Score with Zygel Treatment

As shown in Figure 1 below, compared to their baseline scores, patients on Zygel experienced significant ($P < 0.01$) improvement in their mean ABC-UI beginning at week 4 and this improvement was maintained through weeks 8 and 12.

Figure 1. Mean ABC-UI Score at Each Timepoint during Treatment with Zygel (*P<0.01)



The authors of the poster concluded that:

- Treatment with Zygel significantly improved health state utility index scores in pediatric and adolescent patients with FXS, suggesting a potential broad spectrum of benefit of Zygel in the important domains of the ABC-C_{FXS} that were incorporated into the utility index;
- The correlation of the ABC-UI scores with Clinical Global Impression of Severity (CGI-S) scores in these patients suggests that the ABC-UI appropriately reflects symptom severity in FXS; and
- The estimated health state utility index score of 0.57 in patients with FXS enrolled in FAB-C appear to describe a poor baseline level of HRQoL, despite standard of care, highlighting the considerable impact of FXS symptoms on patient HRQoL.

Fragile X Syndrome Diagnosis and Patient Journey: The Caregiver's Perspective

- *Poster number: 28*
- *Poster presentation time: Tuesday, March 3 from 5:00 to 6:00 PM and Wednesday, March 4 from 5:00 to 7:00 PM.*

"Children with Fragile X syndrome generally remain undiagnosed until approximately three years of age, and the path to diagnosis is complex," said Dr. Palumbo. "These children also have a high prevalence of comorbid conditions which complicates the diagnosis. Today's standard of care includes counseling and therapy and the use of traditional prescription medications that aren't specifically indicated for FXS. This information supports the importance of testing for the disorder early in the diagnostic journey and bringing novel treatments that specifically treat the behavioral symptoms of FXS through the FDA approval process for the benefit of patients and their families."

Core FXS clinical symptoms include social avoidance/withdrawal, anxiety, irritability, deficits in learning and cognition, and sleep difficulties. These symptoms are frequently compounded by comorbid conditions, including autism and attention-deficit/hyperactivity disorder. Parents often first recognize the initial symptoms and developmental delays, leading to subsequent clinical diagnosis of FXS utilizing genetic testing for mutations in the FMR1 gene. Early diagnosis of FXS is important to facilitate treatment and coordinate the multidisciplinary supportive care and educational interventions required to manage the symptoms of FXS. Unfortunately, diagnosis of FXS is often delayed. A 2008 study reported a delay of 24 to 26 months between initial symptoms and diagnosis, and mean age at diagnosis has remained delayed over time (32 months in 2018 vs 38 months in 2008).

Zynerba utilized a 30-minute, anonymized, quantitative online survey, conducted in the United States from May 3 to June 12, 2019, to characterize the patient journey in FXS surrounding diagnosis and clinical experiences. Thirty-five (35) predominantly female (80%) primary caregivers of children with FXS completed the survey. The children of these caregivers were 3 to 17 years of age, had a full FMR1 mutation, and exhibited socially avoidant behaviors.

Path to Diagnosis

The mean age of children with FXS at the time of diagnosis was 36 months. When asked to rate the top 3 factors prompting caregivers to schedule an initial visit with a physician, the most common were:

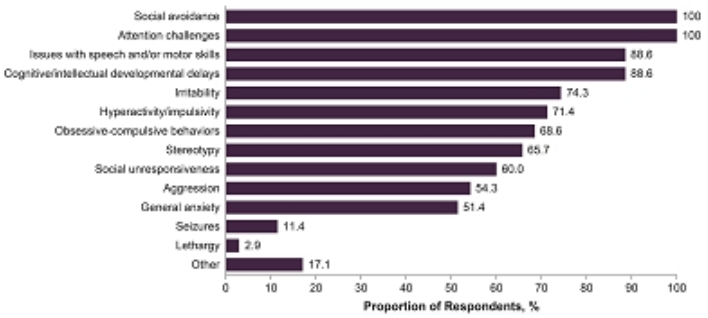
1. Cognitive/intellectual developmental delays;
2. Issues with speech and/or motor skills; and
3. Social avoidance/social unresponsiveness.

Most caregivers scheduled an initial visit with a physician within 6 months of noticing symptoms (82.9%). The first physician seen was usually a primary care physician (family doctor or general pediatrician, 71.4%), but formal diagnosis of FXS was most often made by a specialist (80.0%), most frequently geneticists and neurologists/pediatric neurologists.

Current Experience with FXS

As shown in Figure 2 below, the most frequently experienced current symptoms of FXS were social avoidance and attention challenges. Most caregivers (85.7%) rated the severity of FXS at the time of the survey as severe (45.7%) or moderate (40.0%).

Figure 2. Current FXS Symptoms



Children of the surveyed caregivers were receiving a mean 1.94 treatments. Seventy-seven (77%) of children were currently receiving counseling/therapy; 46% were receiving traditional prescription treatment; and 31.4% were receiving nonprescription treatment/supplements. The most commonly received prescription medications were antidepressants/selective serotonin reuptake inhibitors (SSRIs) and stimulants. In addition, 77% of the children were reported to have comorbid conditions, the most common being autism spectrum disorder (66%), attention-deficit/hyperactivity disorder (26%), and sleep disorders (20%).

The authors concluded that:

- The results of this survey expanded upon existing knowledge of the initial presentation/diagnosis and experience of FXS, finding an average age of 3 years at initial diagnosis, a high prevalence of comorbid conditions, and standard of care consisting primarily of counseling/therapy and traditional prescription medications; and
- While caregivers of children with FXS often notice a variety of initial symptoms early and seek help from a health care professional, it is not until subsequent physician visits, often involving a specialist, that a formal diagnosis is made.

About Zynerba Pharmaceuticals, Inc.

Zynerba Pharmaceuticals is the leader in pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders. We are committed to improving the lives of patients and their families living with severe, chronic health conditions including Fragile X syndrome, autism spectrum disorder, 22q11.2 deletion syndrome, and a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies. Learn more at www.zynerba.com and follow us on Twitter at @ZynerbaPharma.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company’s current expectations. Management’s expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: the Company’s cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the Company’s ability to obtain additional funding to support its clinical development programs; the results, cost and timing of the Company’s clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; clinical results for the Company’s product candidates may not be replicated or continue to occur in additional trials and may not otherwise support further development in a specified indication or at all; actions or advice of the U.S. Food and Drug Administration and foreign regulatory agencies may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional clinical trials; the Company’s ability to obtain and maintain regulatory approval for its product candidates, and the labeling under any such approval; the Company’s reliance on third parties to assist in conducting pre-clinical and clinical trials for its product candidates; delays, interruptions or failures in the manufacture and supply of the Company’s product candidates the Company’s ability to commercialize its product candidates; the size and growth potential of the markets for the Company’s product candidates, and the Company’s ability to service those markets; the Company’s ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company’s product candidates; the Company’s expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates; and the timing and outcome of current and future legal proceedings. This list is not exhaustive and these and other risks are described in the Company’s periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Zynerba Pharmaceuticals Presents Data Showing that the Baseline Characteristics of Patients in Phase 2 BRIGHT Trial in Autism Spectrum Disorder Indicate a Moderate-to-Severe Study Population

- New Data Presented Today at the American Society for Experimental Neurotherapeutics (ASENT) 2020 Meeting -

DEVON, Pa., March 3, 2020 – Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, is presenting data this week further describing the baseline characteristics of the pediatric and adolescent patients in the fully-enrolled Phase 2 BRIGHT trial of Zygel™ (CBD transdermal gel; ZYN002) in children and adolescents with autism spectrum disorder (ASD), indicating that the trial enrolled a broad population of patients with moderate-to-severe ASD.

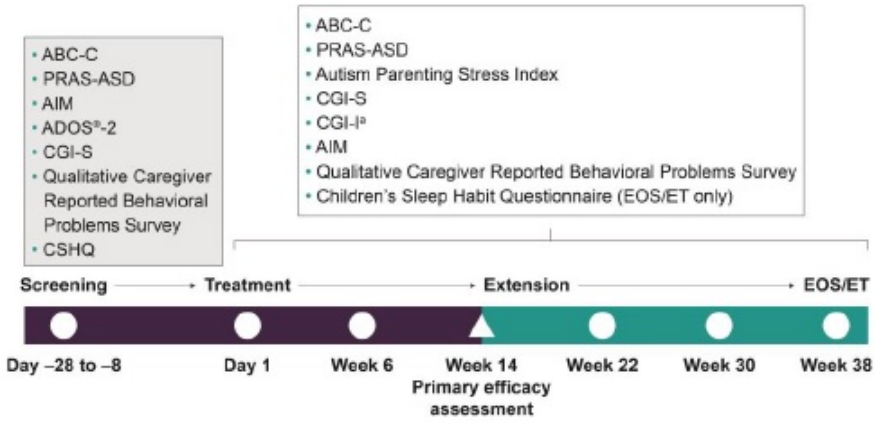
The poster entitled *Phase 2 BRIGHT (An Exploratory Open-La**b**el Tole**r**rab**i**lity and Efficacy Study of ZYN002 Administered as a Transdermal **G**el to C**h**ildren and Adolescen**t**s with Autism Spectrum Disorder) Trial: Baseline Characteristics* (poster #27) is being presented at the American Society for Experimental Neurotherapeutics (ASENT) 2020 Meeting. The poster is being presented on Tuesday, March 3 from 5:00 to 6:00 PM EST and Wednesday, March 4 from 5:00 to 7:00 PM EST. These data will also be presented during the ASENT Pipeline Data Blitz session on Wednesday March 4, 2020 from 1:00 to 3:00PM EST. The meeting is being held In Bethesda, MD on March 2nd through March 5th, 2020. A copy of the poster is available on the Zynerba corporate website at http://zynerba.com/publications/.

Zynerba's Chief Medical Officer, Joseph M. Palumbo, MD, FAPA, MACPsych, is presenting data describing the baseline characteristics of patients enrolled in the ongoing BRIGHT trial, which indicate a patient population with predominantly moderate-to-severe ASD as measured by key scales used for screening and efficacy assessment. These include the Aberrant Behavior Checklist – Community (ABC-C); the Autism Diagnostic Observation Schedule® (ADOS-2); and the Parent Rated Anxiety Scale–Autism Spectrum Disorder (PRAS-ASD).

"ASD is a complex neurodevelopmental disorder characterized by difficulties with behaviors, communication, and social interaction," said Dr. Palumbo. "Pediatric and adolescent patients with ASD may also present with profound clinical anxiety, above the rate seen in neurotypical children, further complicating their condition and treatment regimen. Unfortunately, current ASD management options are restricted to cognitive behavioral therapy and a small number of approved pharmacologic treatments, highlighting the substantial unmet need for novel therapies in this population. We believe that we have enrolled an appropriate population of patients into our well-designed exploratory BRIGHT trial to enable a robust analysis of outcomes to help inform the design of future double-blind, placebo-controlled studies."

The endocannabinoid system - a key modulator of emotion and social behavior - is dysregulated in ASD, and published data suggest that cannabidiol (CBD) may provide therapeutic benefit. However, the efficacy and safety of CBD in patients with ASD have not been well established. Zynerba is undertaking the 14-week BRIGHT Phase 2 exploratory trial in children and adolescents (ages four through 17 years) with ASD as confirmed by Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) diagnostic criteria to assess the safety and efficacy of Zygel in treating ASD-related behaviors as measured by a variety of efficacy assessments which are shown in Figure 1, below. After completing dosing in the 14-week period, participants may enroll in a six-month extension trial.

Figure 1. Schedule of Screening and Efficacy Assessments



The trial protocol included certain inclusion and exclusion criteria to enrich the trial population for disease severity at baseline, as measured by the following assessments:

ABC-C

- A 58-item caregiver-rated scale measuring behaviors across 5 subscales: irritability/agitation (maximum score: 45), lethargy/social withdrawal (maximum score: 48), stereotypic behavior (maximum score: 21), hyperactivity/noncompliance (maximum score: 48), inappropriate speech (maximum score: 12);
- Each behavior is scored from 0 ("not at all a problem") to 3 ("the problem is severe in degree");
- Higher scores indicate greater severity of aberrant behavior.

ADOS-2

- A diagnostic tool consisting of 5 age and verbal ability - dependent modules that assess social communication and core behaviors of ASD;
- Each item is scored by a trained test administrator from 0 ("no abnormality of type specified") to 3 ("moderate to severe abnormality");
- ADOS total scores are diagnostic; however, standardized comparison scores can be used to measure severity;
- Comparison scores range from 0-10, with scores of <5 indicating mild ASD, scores of 5-7 indicating moderate ASD, and scores of 8-10 indicating severe ASD.

PRAS-ASD

- A 25-item parent-rated scale assessing anxiety in ASD;
- Each item is scored from 0 (“not present”) to 3 (“very frequent and a major problem”);
- Maximum score is 75, with scores >52 indicating possible clinical anxiety.

Baseline Disease Characteristics

As seen in Table 1 below, the majority of patients had moderate or severe ASD at baseline as measured by the ADOS-2 comparison score (94%) and DSM-5 severity levels (92%). In addition, the mean ABC-C Irritability score was 30.0, and 24% of the enrolled patients had PRAS-ASD scores indicative of possible clinical anxiety, further highlighting the severity of symptoms in the enrolled patient population.

Table 1. Baseline Disease Characteristics of Patients Enrolled in BRIGHT

Disease Characteristics	**Patients in BRIGHT N=37**
ABC-C Irritability Subscale score (0-45)	
n	37
Mean (range)	30.0 (18-43)
PRAS-ASD score (0-75; >52 suggests possible clinical anxiety)	
n	37
Mean (range)	40.9 (21-68)
>52, n (%)	9 (24.3)
DSM-5 severity level[i]	
Level 1 (mild), n (%)	3 (8.1)
Level 2 (moderate), n (%)	15 (40.5)
Level 3 (severe), n (%)	19 (51.4)
ADOS®-2 comparison score	
n	36
Mean (range)	7.5 (4-10)
<5 (mild ASD), n (%)	2 (5.6)
5-7 (moderate ASD), n (%)	19 (52.8)
8-10 (severe ASD), n (%)	15 (41.7)

The authors conclude that the Phase 2 BRIGHT trial has successfully enrolled a broad patient population and was enriched for disease severity to avoid floor effects on outcome measures. The baseline characteristics indicate a patient population with predominantly moderate-to-severe ASD, with a high level of clinically significant anxiety.

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[i] DSM-5 severity levels are based on degree of social communication impairment and behavioral flexibility. The levels indicate patients “requiring support” (level 1), “requiring substantial support” (level 2), and “requiring very substantial support” (level 3).