



HARMONY BIOSCIENCES TO ACQUIRE ZYNERBA PHARMACEUTICALS, INC.

Aug 14, 2023

Acquisition expands pipeline and diversifies portfolio to drive long-term growth

**Innovative potential new therapeutic option for rare/orphan neuropsychiatric disorders with high unmet medical needs
Lead asset in pivotal Phase 3 trial for Fragile X syndrome and has completed Phase 2 proof-of-concept study in 22q11.2 deletion syndrome**

Conference call and webcast to be held today at 8:30 AM ET

PLYMOUTH MEETING, Pa. and DEVON, Pa., Aug. 14, 2023 /PRNewswire/ -- Harmony Biosciences Holdings, Inc. ("Harmony") (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients with rare neurological diseases, today announced a definitive agreement to acquire Zynerba Pharmaceuticals, Inc. ("Zynerba") (Nasdaq: ZYNE), a leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for orphan neuropsychiatric disorders, including Fragile X syndrome (FXS).



Under the terms of the definitive agreement, Harmony will commence a tender offer to acquire all outstanding shares of Zynerba for a purchase price of \$1.1059 per share in cash, or \$60 million in the aggregate, plus one non-tradeable contingent value right (CVR) per share, representing the right to receive potential additional payments of up to \$140 million in the aggregate, subject to the achievement of certain clinical, regulatory and sales milestones, as described in more detail below.

"This is an important step in Harmony's strategy to build a diversified portfolio of innovative assets to address unmet medical needs and drive our long-term growth. This acquisition affords us the opportunity to advance the development and delivery of a potentially transformative treatment for the symptoms of Fragile X syndrome and other rare neuropsychiatric disorders," said Jeffrey M. Dayno, M.D., President and Chief Executive Officer at Harmony Biosciences. "In addition to the strength of our core business in narcolepsy and our current life cycle management programs, led by idiopathic hypersomnia, we are excited to continue to diversify our portfolio beyond sleep/wake by adding Zynerba's clinical development programs to our pipeline. The team at Zynerba has been dedicated to these programs and we are confident that our combined efforts could have a profound impact on individuals living with rare neuropsychiatric disorders and their families."

"Harmony's development and commercial expertise, technologies, people and focus on rare neurological diseases are an excellent strategic fit with Zynerba," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "I am very proud of Zynerba's accomplishments with Zygel™ to date. With Harmony's scale, resources and proven commercial excellence, they are well positioned to potentially bring to market the first pharmaceutical product indicated for the treatment of behavioral symptoms of Fragile X syndrome and to maximize the value of Zygel."

Zynerba's lead asset, Zygel, is the first and only pharmaceutically manufactured, synthetic cannabidiol, a non-euphoric cannabinoid, formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system. Zygel is manufactured through a synthetic process in a cGMP facility and is not extracted from the cannabis plant. Therefore, it is devoid of THC, which is what causes the euphoric effect of cannabis, and has the potential to be a nonscheduled product if approved. Zygel is currently being evaluated in a pivotal Phase 3 clinical trial for patients living with FXS, known as the RECONNECT Trial. Additionally, Zygel showed positive signals in an open label Phase 2 trial in patients living with 22q11.2 deletion syndrome (22q), called the INSPIRE Trial.

Cannabidiol, the active ingredient in Zygel, has been granted orphan drug designation by the United States Food and Drug Administration (FDA) and

the European Medicines Agency (EMA) for the treatment of FXS and for the treatment of 22q. Additionally, Zygel has received FDA Fast Track designation for the treatment of behavioral symptoms in patients with FXS.

FXS is a rare genetic disorder that affects approximately 80,000 people in the U.S., causing intellectual disabilities and behavioral challenges. Despite considerable progress in medical science, there remains a significant unmet medical need in treating patients living with this debilitating disorder. There are currently no FDA approved therapies to treat FXS.

It is estimated that there are approximately 80,000 people living with 22q in the U.S. Patients with 22q are affected by symptoms related to many organ systems including neuropsychiatric symptoms such as anxiety and behavioral difficulties. There are currently no FDA-approved therapies to treat 22q.

Transaction Details

Under the terms of the definitive agreement, which was unanimously approved by the boards of directors of Harmony and Zynerba, Harmony will commence a tender offer to acquire all outstanding shares of Zynerba for a purchase price of \$1.1059 in cash per share, or \$60 million in the aggregate payable at closing of the transaction plus one non-tradeable CVR representing the right to receive potential additional payments of up to \$140 million or approximately \$2.5444 in additional cash per share, for a total potential consideration of up to \$200 million in cash. The CVR is payable subject to certain terms and conditions upon achievement of the following milestones:

Clinical Milestones

- Completion of FXS Phase 3 clinical trial: \$15 million in the aggregate or approximately \$0.2747 per share
- Positive data readout from FXS Phase 3 clinical trial:

\$30 million in the aggregate or approximately \$0.5494 per share if completed on or before December 31, 2024

\$20 million in the aggregate or approximately \$0.3663 per share if completed on or before June 30, 2025

\$10 million in the aggregate or approximately \$0.1831 per share if completed after June 30, 2025

Regulatory Milestones

- FDA approval in FXS: \$35 million in the aggregate or approximately \$0.6389 per share
- FDA approval in Second Indication: \$15 million in the aggregate or approximately \$0.2707 per share

Net Sales Milestones

- Achievement of \$250 million in aggregate Net Sales: \$15 million in the aggregate or approximately \$0.2702 per share
- Achievement of \$500 million in aggregate Net Sales: \$30 million in the aggregate or approximately \$0.5405 per share

Each CVR is subject to the achievement of the milestone conditions described above, and there can be no assurance whether any such milestones will be achieved or when any payments will be made with respect to any CVR.

Harmony will fund the transaction from its existing cash on hand. As of June 30, 2023, Harmony had cash, cash equivalents and investment securities of \$429.6 million. Zynerba's existing cash and cash equivalent balance was approximately \$36.0 million as of June 30, 2023.

The transaction is expected to close by the fourth quarter of 2023, subject to customary closing conditions, including that the holders of at least a majority of the outstanding shares of Zynerba's common stock tender such shares to Harmony in connection with the tender offer. Following the successful closing of the tender offer, Harmony will acquire any shares of Zynerba it does not already own through a second-step merger at the same per share offer price as paid in the tender offer. Zynerba's board of directors unanimously recommends that Zynerba's stockholders tender their shares in the tender offer.

Advisors

For Harmony, Hogan Lovells US LLP is acting as legal counsel. For Zynerba, MTS Health Partners, L.P. is acting as financial advisor and Goodwin Procter LLP is acting as legal counsel.

Conference Call Today at 8:30 AM ET

At 8:30 AM ET Harmony will host a live webcast to review this proposed acquisition. The live and replay webcast of the call will be available on the investor relations page of our website at <https://ir.harmonybiosciences.com/>. To participate in the live call by phone, dial (800) 245-3047 (domestic) or +1 (203) 518-9765 (international), and reference passcode HRMY0814.

About Harmony Biosciences

At Harmony Biosciences, we specialize in developing and delivering treatments for rare neurological diseases that others often overlook. We believe that where empathy and innovation meet, a better life can begin for people living with neurological diseases. Established by Paragon Biosciences, LLC, in 2017 and headquartered in Plymouth Meeting, PA, our team of experts from a wide variety of disciplines and experiences is driven by our shared conviction that innovative science translates into therapeutic possibilities for our patients, who are at the heart of everything we do. For more information, please visit www.harmonybiosciences.com.

About Zynerba Pharmaceuticals, Inc.

Zynerba Pharmaceuticals is the leader in innovative pharmaceutically produced, synthetic transdermal cannabidiol therapies for orphan neuropsychiatric disorders. We are committed to improving the lives of patients and their families living with severe, chronic health conditions including Fragile X syndrome and 22q11.2 deletion syndrome. Learn more at www.zynerba.com.

About Fragile X Syndrome

Fragile X syndrome (FXS) is a rare genetic disorder that is the leading known cause of both inherited intellectual disability and autism spectrum disorder, affecting 1 in 3,600 to 4,000 males and 1 in 4,000 to 6,000 females. The disorder negatively affects synaptic function, plasticity and neuronal connections, and results in a spectrum of intellectual disabilities and behavioral symptoms, such as social avoidance and irritability. There are approximately 80,000 people in the U.S. and approximately 121,000 people in the European Union and UK living with FXS. There is a significant

unmet medical need in patients living with FXS as there are currently no FDA approved treatments for this disorder.

FXS is caused by a mutation in FMR1, a gene which modulates a number of systems, including the endocannabinoid system, and most critically, codes for a protein called FMRP. The FMR1 mutation manifests as multiple repeats of a DNA segment, known as the CGG triplet repeat, resulting in deficiency or lack of FMRP. FMRP helps regulate the production of other proteins and plays a role in the development of synapses, which are critical for relaying nerve impulses, and in regulating synaptic plasticity. In people with full mutation of the FMR1 gene, the CGG segment is repeated more than 200 times, and in most cases causes the gene to not function. Methylation of the FMR1 gene also plays a role in determining functionality of the gene. In approximately 60% of patients with FXS, who have complete methylation of the FMR1 gene, no FMRP is produced, resulting in dysregulation of the systems modulated by FMRP.

About 22q11.2 Deletion Syndrome

22q11.2 deletion syndrome (22q) is a disorder caused by a small missing piece of the 22nd chromosome. The deletion occurs near the middle of the chromosome at a location designated q11.2. It is considered a mid-line condition, with physical symptoms including characteristic palate abnormalities, heart defects, immune dysfunction, and esophageal / GI issues, as well as debilitating neuropsychiatric and behavioral symptoms, including anxiety, social withdrawal, ADHD, cognitive impairment and autism spectrum disorder. It is estimated that 22q occurs in one in 4,000 live births, suggesting that there are approximately 80,000 people living with 22q in the U.S. and 129,000 in the European Union and the UK. Patients with 22q deletion syndrome are managed by multidisciplinary care providers, and there are currently no FDA approved treatments for this disorder.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements, including as they relate to Harmony and Zynerba, the anticipated occurrence, manner and timing of the proposed transaction, the future development of their technologies and product candidates, including the development of and market opportunities for Zynerba's technology and product candidates, the future value (if any) of the contingent value rights, Harmony's strategy, and the anticipated synergies and benefits from the proposed transaction, are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Potential risks, uncertainties and other factors to be considered include, among others, that Zynerba stockholders may not tender a sufficient number of shares in the tender offer; the length of time necessary to consummate the proposed transaction may be longer than anticipated, or it may not be consummated at all; problems may arise in successfully integrating the business and technologies of Harmony and Zynerba, and Harmony may not realize the expected benefits of the proposed transaction; the proposed transaction may involve unexpected costs; the businesses may suffer as a result of uncertainty surrounding the proposed transaction, including difficulties in maintaining relationships with third parties or retaining key employees; and even if the transaction is consummated no contingent consideration may become payable. For further discussion of these and other risks and uncertainties, see Harmony's and Zynerba's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission (the "SEC"), including under the headings "Risk Factors." You are cautioned to not place undue reliance on forward-looking statements, which speak only as of the date of this document. Except as required by law, neither Harmony nor Zynerba is under any duty to update any of the information in this document.

Additional Information about the Acquisition and Where to Find It:

In connection with the proposed acquisition, Harmony will commence a tender offer for the outstanding shares of Zynerba. The tender offer has not yet commenced. This document is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Zynerba, nor is it a substitute for the tender offer materials that Harmony and Xylophone Acquisition Corp ("Purchaser") will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Harmony and Purchaser will file tender offer materials on Schedule TO, and Zynerba will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. Holders of shares of Zynerba common stock are urged to read the tender offer materials (including an Offer to Purchase, a related Letter of Transmittal and certain other tender offer documents) and the Solicitation/Recommendation Statement when they become available (as each may be amended or supplemented from time to time) because they will contain important information that holders of shares of Zynerba common stock should consider before making any decision regarding tendering their shares. The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Zynerba at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC's website at www.sec.gov. In addition, these materials will be available at no charge on the Enhanced SEC Filings section of the Investor Relations page of Zynerba's website at <https://www.zynerba.com/> and by directing a request to the information agent for the tender offer, whose information will be set forth in the Offer to Purchase.

Harmony Biosciences Contacts:

Investor:

Luis Sanay, CFA
445-235-8386
lsanay@harmonybiosciences.com

Media:

Cate McCanless
202-641-6086
cmccanless@harmonybiosciences.com

Zynerba Pharmaceuticals Contact:

Peter Vozzo
ICR Westwicke
443-213-0505
Peter.Vozzo@westwicke.com

[pharmaceuticals-inc-301899483.html](https://www.fda.gov/oc/ohrt/pharmaceuticals-inc-301899483.html)

SOURCE Harmony Biosciences and Zynerba Pharmaceuticals, Inc.