

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

FORM 8-K

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

Date of report (Date of earliest event reported): October 10, 2023

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39450
(Commission
File Number)

82-2279923
(IRS Employer
Identification No.)

630 W. Germantown Pike, Suite 215
Plymouth Meeting, PA 19462
(Address of principal executive offices) (Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

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, par value \$0.00001 per share	HRMY	The Nasdaq Global Market LLC (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 2.01. Completion of Acquisition or Disposition of Assets.

On October 10, 2023, Harmony Biosciences Holdings, Inc. (the “Company”) completed the previously announced acquisition of Zynerba Pharmaceuticals, Inc. (“Zynerba”), pursuant to an Agreement and Plan of Merger, dated as of August 14, 2023, and amended on October 4, 2023 (the “Merger Agreement”), by and among Zynerba, the Company and Xylophone Acquisition Corp. (“Purchaser”). All capitalized terms used herein and not otherwise defined have the meanings given to such terms in the Merger Agreement.

As previously disclosed in the Current Report on Form 8-K filed with the Securities and Exchange Commission (the “SEC”), as amended, pursuant to the Merger Agreement, Purchaser commenced a tender offer (the “Offer”) to acquire all of the outstanding shares of common stock of Zynerba, par value \$0.001 per share (the “Shares”), at a price of (i) \$1.1059 per Share (the “Closing Amount”), in cash, subject to any applicable withholding of taxes and without interest, plus (ii) one contingent value right (each, a “CVR”) per Share, which represents the right to receive up to approximately \$2.5444 per Share in the form of one or more potential contingent payments, in cash, subject to any applicable withholding of taxes and without interest, upon the achievement of certain milestones as set forth in, and subject to and in accordance with the terms and conditions of, the CVR Agreement (as defined below) (the Closing Amount plus one CVR, the “Offer Price”), upon the terms and subject to the conditions set forth in the Offer to Purchase, filed by the Company and Purchaser with the United States Securities and Exchange Commission (the “SEC”) on August 28, 2023, as amended or supplemented from time to time.

The Offer and withdrawal rights expired at 5:00 p.m., New York City Time, on October 10, 2023 (such date and time, the “Expiration Time”) and was not extended. According to Equiniti Trust Company, LLC, the depository for the Offer (the “Depository”), 28,236,148 Shares were validly tendered and not validly withdrawn, representing approximately 52.3% of the issued and outstanding Shares as of the Expiration Time (not including 1,072,940 shares delivered through Notices of Guaranteed Delivery, representing approximately 2.0% of the shares outstanding). As of the Expiration Time, a sufficient number of Shares were validly tendered and not validly withdrawn such that the Minimum Condition (as defined in the Merger Agreement) was satisfied. Each condition to the Offer was satisfied or waived, and on October 10, 2023, Purchaser irrevocably accepted for payment all Shares that were validly tendered and not validly withdrawn pursuant to the Offer. The Purchaser will promptly pay for all Shares accepted for payment pursuant to the Offer.

On October 10, 2023, following consummation of the Offer, the remaining conditions to the Merger (as defined below) were satisfied and Purchaser merged with and into Zynerba (the “Merger”), with Zynerba surviving as a direct wholly owned subsidiary of the Company (the “Surviving Corporation”). The Merger was governed by Section 251(h) of the General Corporation Law of the State of Delaware (the “DGCL”), with no vote of the stockholders of Zynerba required to consummate the Merger. At the effective time of the Merger (the “Effective Time”), each Share (other than Shares (i) held in the treasury of Zynerba, (ii) that as of the commencement of the Offer were owned by the Company or Purchaser, (iii) irrevocably accepted for payment in the Offer and/or (iv) held by holders who have properly exercised their appraisal rights under the DGCL) was automatically converted into the right to receive the Offer Price, without interest and subject to any withholding of applicable taxes.

In addition, immediately prior to the Effective Time, by virtue of the Merger and without any action on the part of any holder thereof:

- Each of Zynerba’s stock options (“Zynerba Option”), whether vested or unvested, that had a per share exercise price that was less than the Closing Amount that was outstanding and unexercised immediately prior to the Effective Time, was cancelled and converted into the right to receive for each Share underlying such Zynerba Option, without interest and subject to deduction for any required withholding under applicable tax law, (i) an amount in cash equal to the excess of the Closing Amount over the per share exercise price of such Zynerba Option and (ii) one CVR;
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- Each Zynerba Option that had a per share exercise price that was equal to or greater than the Closing Amount but less than \$2.71, whether vested or unvested, that was outstanding and unexercised immediately prior to the Effective Time was cancelled and automatically converted into the right to receive, for each Share underlying such Zynerba Option, without interest and subject to deduction for any required withholding under applicable tax law, upon the occurrence of any Milestone Payment (as defined in the CVR Agreement) a cash payment, if any, equal to (i) the amount, if any, by which (A) the Closing Amount plus the applicable Milestone Payment *plus* any Milestone Payment that was previously paid in respect of a Share exceeds (B) the per share exercise price of such Zynerba Option, *minus* (ii) the gross amount of Milestone Payments previously paid with respect to such Share underlying such Zynerba Option.
- Each Zynerba Option that had a per share exercise price equal to or greater than \$2.71 was cancelled at the Effective Time without any consideration payable therefore (whether in the form of cash, a CVR or otherwise).
- Each restricted stock award of Zynerba (a “Zynerba Restricted Stock Award”) that was (x) outstanding immediately prior to the Effective Time and (y) of which the underlying shares of common stock of the Company were not validly tendered in the Offer, whether vested or unvested, was cancelled and automatically converted into the right to receive for each Share subject to a Zynerba Restricted Stock Award, without interest and subject to deduction for any required withholding under applicable tax law, (i) an amount in cash equal to the Closing Amount and (ii) one CVR.

Following the consummation of the Offer, the Company and the Rights Agent (as defined in the CVR Agreement) entered into a Contingent Value Rights Agreement (the “CVR Agreement”), dated October 10, 2023 governing the terms of the CVRs to be received by Zynerba’s stockholders and holders of certain Zynerba Options and Zynerba Restricted Stock Awards. The CVRs represent the right to receive contingent payments, payable to the Rights Agent for the benefit of the holders of CVRs, if the following milestones are achieved (each, a “Milestone”):

- Milestone 1: An aggregate milestone payment of \$15,000,000, payable upon the completion of the last patient’s last visit in the RECONNECT (ZYN2-CL-033) clinical trial (the “Pivotal Study”) for Zygel(TM) (ZYN002) (the “Product”) by or before June 30, 2026;
- Milestone 2: upon the completion of the Pivotal Study for the Product and a finding that the data from such Pivotal Study meet the primary end point(s) with statistical significance as set forth in the protocol of such Pivotal Study (“Milestone 2”), an aggregate milestone payment of (i) \$30,000,000, with respect to the achievement of Milestone 2 by or before December 31, 2024; (ii) \$20,000,000, with respect to the achievement of Milestone 2 between January 1, 2025 and June 30, 2025; or (iii) \$10,000,000, with respect to the achievement of Milestone 2 on or after July 1, 2025;
- Milestone 3: An aggregate milestone payment of \$35,000,000, payable upon the achievement of NDA Approval (as defined in the CVR Agreement) with respect to the Product in the First Indication (as defined in the CVR Agreement) (“Milestone 3”)
- Milestone 4: An aggregate milestone payment of \$15,000,000, payable upon the achievement of NDA Approval (as defined in the CVR Agreement) with respect to the Product in the Second Indication (as defined in the CVR Agreement);
- Milestone 5: An aggregate milestone payment of \$15,000,000, payable upon the achievement of worldwide aggregate Net Sales (as defined in the CVR Agreement) of the Product (inclusive of all Indications (as defined in the CVR Agreement)) of at least \$250,000,000, calculated on a cumulative basis for all Calendar Years (as defined in the CVR Agreement) (or portion thereof), provided that Milestone 3 is achieved by or before December 31, 2030 (“Milestone 5”); and
- Milestone 6: An aggregate milestone payment of \$30,000,000, payable upon the achievement of worldwide aggregate Net Sales of the Product (inclusive of all Indications) prior to of at least \$500,000,000, calculated on a cumulative basis for all Calendar Years (or portion thereof) and inclusive of all Net Sales applied toward achievement of Milestone 5, provided that Milestone 3 is achieved by or before December 31, 2030.

The right to the contingent consideration as evidenced by the CVR Agreement is a contractual right only. The CVRs will not be transferable, except in the limited circumstances specified in the CVR Agreement, will not be evidenced by certificate or other instrument and will not be registered or listed for trading. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in the Company or Zynerba.

The CVR Agreement and the rights of holders of CVRs to receive Milestone payments thereunder will terminate on December 31, 2040. There can be no assurance whether or when any of the Milestones will be achieved and that any of the resulting Milestone payments will be required of the Company. Each Milestone with respect to a CVR may only be achieved one time. The minimum payment on the CVR is zero and the maximum payment is \$2.5444 in cash per CVR.

The foregoing description of the CVR Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the form of CVR Agreement, which is provided as Exhibit B of the Merger Agreement, which is attached to this Current Report on Form 8-K as Exhibit 2.1 and incorporated herein by reference.

The foregoing summary of the Offer, the Merger, the Merger Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Merger Agreement, which is incorporated herein by reference and attached as Exhibit 2.1 to this Current Report on Form 8-K.

Item 7.01. Regulation FD Disclosure.

On October 11, 2023, the Company issued a press release relating to the consummation of the Merger. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

The audited financial statements of Zynerba, to the extent required by this item, will be filed by amendment to this Current Report on Form 8-K no later than 71 calendar days after the date on which this Current Report on Form 8-K was required to be filed.

(b) Pro Forma Financial Information.

The pro forma financial information reflecting the Merger, to the extent required by this item, will be filed by amendment to this Current Report on Form 8-K no later than 71 calendar days after the date on which this Current Report on Form 8-K was required to be filed.

(d) Exhibits

Exhibit No.	Description
2.1*	Agreement and Plan of Merger, dated August 14, 2023, by and among Harmony Biosciences Holdings, Inc., Xylophone Acquisition Corp. and Zynerba Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to Harmony Biosciences Holdings, Inc.'s Current Report on Form 8-K/A, filed on September 14, 2023).
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of October 4, 2023, by and among Harmony Biosciences Holdings, Inc., Xylophone Acquisition Corp. and Zynerba Pharmaceuticals, Inc. (incorporated by reference to Exhibit (d)(5) of Harmony Biosciences Holdings, Inc.'s Schedule TO Amendment No. 3, filed on October 5, 2023).
99.1**	Press release issued by the Company, dated October 11, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 for any schedules so furnished.

** This Exhibit is furnished herewith and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act except to the extent that Harmony Biosciences Holdings, Inc. specifically incorporates it by reference.

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.

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: October 11, 2023

By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer



**HARMONY BIOSCIENCES COMPLETES ACQUISITION OF ZYNERBA
PHARMACEUTICALS AND EXPANDS PIPELINE**

New product in development diversifies portfolio to drive long-term growth

Innovative potential new therapeutic option for rare/orphan neuropsychiatric disorders with high unmet medical needs

Zygel™ in pivotal Phase 3 trial for Fragile X syndrome and has completed Phase 2 proof-of-concept study in 22q11.2 deletion syndrome

PLYMOUTH MEETING, Pa., October 11, 2023 — 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 that it has completed its acquisition of Zynerba Pharmaceuticals, Inc. (“Zynerba”) (Nasdaq: ZYNE).

Zynerba is a leader in pharmaceutically produced transdermal cannabinoid therapies for orphan neuropsychiatric disorders. Harmony President & CEO Jeffrey M. Dayno, MD, described its lead candidate, Zygel, as a ‘portfolio in a product’ with the potential to serve 80,000 U.S. patients who are diagnosed with Fragile X syndrome (FXS) and another 80,000 diagnosed with 22q deletion syndrome (22q).

“Zygel is a significant market opportunity that advances our long-term growth strategy of developing a diversified portfolio beyond sleep/wake therapies,” Dayno said. “This acquisition expands our pipeline with a product candidate in our area of expertise that could address high unmet medical needs for people living with rare neuropsychiatric disorders.”

Zygel is the first-and-only pharmaceutically manufactured synthetic cannabidiol. It is a non-euphoric cannabinoid formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system. The product is manufactured through a synthetic process in a cGMP facility and is not extracted from the cannabis plant.

Zygel does not contain THC, the compound that causes the euphoric effect of cannabis, and has the potential to be a nonscheduled product if approved.

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.

Harmony's 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 or approximately \$2.5444 in additional cash per share, subject to the achievement of certain clinical, regulatory and sales milestones, expired at 5:00 p.m. New York City time on Tuesday, October 10, 2023. The depositary for the tender offer has advised that, as of the expiration of the tender offer, a total of 28,236,148 shares of Zynerba's common stock were validly tendered and not withdrawn in the tender offer, which represent approximately 52.3% of the total number of shares of Zynerba's outstanding common stock (not including 1,072,940 shares delivered through Notices of Guaranteed Delivery, representing approximately 2.0% of the shares outstanding).

Following the acceptance of the tendered shares, Harmony completed the acquisition of Zynerba through the merger of a wholly owned subsidiary of Harmony with and into Zynerba in which each share of Zynerba's common stock issued and outstanding immediately prior to consummation of the merger (other than shares (a) held in Zynerba's treasury, (b) owned by Harmony at the time the offer commenced, (c) irrevocably accepted for payment in the tender offer or (d) shares held by Zynerba stockholders who properly demanded appraisal for their shares under Delaware law), including shares granted under Zynerba's equity compensation arrangements that were not validly tendered in the tender offer, was converted into the right to receive \$1.1059 per share in cash plus one CVR. As a result of the merger, Zynerba became a wholly owned subsidiary of Harmony. The common stock of Zynerba will no longer be listed for trading on the Nasdaq Capital Market.

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 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 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 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, problems may arise in successfully integrating the business and technologies of Harmony and Zynerba, and Harmony may not realize the expected benefits of the transaction; the transaction may involve unexpected costs; the businesses may suffer as a result of uncertainty surrounding the transaction, including difficulties in maintaining relationships with third parties or retaining key employees; and 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.

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