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): August 10, 2021

HARMONY BIOSCIENCES HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39450**	**82-2279923**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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, $0.00001 par value per share	**HRMY**	**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 2.02. Results of Operations and Financial Condition.

On August 10, 2021, Harmony Biosciences Holdings, Inc. (the "Company") held a conference call regarding its financial results for the quarter ended June 30, 2021. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On August 10, 2021, the Company posted an investor presentation to its website at https://ir.harmonybiosciences.com (the "Investor Presentation"). A copy of the Investor Presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Investor Presentation speaks only as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Investor Presentation, although it may do so from time to time. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. In addition, the exhibit furnished herewith contains statements intended as "forward-looking statements" that are subject to the cautionary statements about forward-looking statements set forth in such exhibit. By furnishing the information contained in the Investor Presentation, the Company makes no admission as to the materiality of any information in the Investor Presentation that is required to be disclosed solely by reason of Regulation FD.

This Current Report on Form 8-K and its contents (including Exhibits 99.1 and 99.2) are furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K constitute "forward-looking statements" within the meaning of the federal securities laws. These statements are based on management's current opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results. These forward-looking statements are only predictions, not historical fact, and involve certain risks and uncertainties, as well as assumptions. Actual results, levels of activity, performance, achievements and events could differ materially from those stated, anticipated or implied by such forward-looking statements. While the Company believes that its assumptions are reasonable, it is very difficult to predict the impact of known factors, and, of course, it is impossible to anticipate all factors that could affect actual results. There are many risks and uncertainties that could cause actual results to differ materially from forward-looking statements made herein including the risks discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 25, 2021, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, which was filed with the SEC on August 10, 2021, as well as other factors described from time to time in the Company's filings with the SEC. Such forward-looking statements are made only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update or revise any forward-looking statement because of new information, future events or otherwise, except as otherwise required by law. If it does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1*	Transcript of Conference Call held by the Company on August 10, 2021.
99.2*	Investor Presentation dated August 10, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* 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: August 10, 2021

By: /s/ John C. Jacobs
John C. Jacobs
President and Chief Executive Officer

Conference Call Transcript
Harmony Biosciences Holdings, Inc.
Earnings Conference Call — Second Quarter 2021
August 10, 2021 // 8:30 am (ET)

Operator

Good day, and thank you for standing by. Welcome to the Second Quarter 2021 Financial and Business Update Conference Call. At this time, all participant lines are in a listen-only mode. After the speakers' presentation, there will be a question-and-answer session. [Operator instructions] Please be advised that today's conference is being recorded. [Operator Instructions].

I would now like to hand the conference over to your speaker, Lisa Caperelli, Head of Investor Relations.

Lisa Caperelli

Thank you, operator. Good morning, everyone, and thank you for joining us today as we review Harmony Biosciences' second quarter 2021 financial performance, and provide business updates.

Before we start, I encourage everyone to go to the Investors section of the Harmony Biosciences website to find the press release and Slides that accompany our discussion today, including a reconciliation of our GAAP to non-GAAP financial measures. At this stage of our life cycle, we believe non-GAAP financial results better represent the underlying economics of our business.

Our presenters on today's call are John Jacobs, President and CEO; Dr. Jeff Dayno, Chief Medical Officer; Jeff Dierks, Chief Commercial Officer; and Sandip Kapadia, CFO.

Moving on to Slide 2, as a reminder, we will be making forward-looking statements today, which are based on our current expectations and beliefs. These statements are subject to certain risks and uncertainties, and our actual results may differ materially. I encourage you to consult the risk factors referenced in our SEC filings for additional details.

At this time, I would like to turn the call over to our CEO, John Jacobs. John?

John Jacobs

Thank you, Lisa. And I would also like to extend my sincere thanks to all of the participants for joining our second quarter 2021 conference call today. We are halfway through the year, and I'm extremely pleased with the progress our team has made to date. Please allow me to elaborate on our achievements in the context of our three pillars growth strategy, which is shown on Slide 3. Pillar One, optimize the commercial performance of WAKIX. Q2 represented a strong quarter for Harmony, as we delivered nearly $74 million in net sales for WAKIX, and achieved our second profitable quarter in company history. This significant growth, nearly 24% versus the prior quarter Q1, was driven by a continued increase in the average number of patients on WAKIX, and in the number of healthcare professionals prescribing our product, both of which further underscore the significant unmet medical need in this market for a truly novel mechanism of action, and differentiated product profile, which WAKIX provides.

Moving on to Pillar Two. Pillar Two is expand the clinical utility of WAKIX beyond narcolepsy. And we are excited to now be evaluating pitolisant in two additional rare disease patient populations beyond narcolepsy, both with significant unmet medical need, and where there are no or limited approved therapies. In addition to our Phase 2 clinical trial in patients with Prader-Willi syndrome that we initiated at the end of last year, in Q2 we initiated a Phase 2 trial in patients with myotonic dystrophy. We're also considering additional indications for WAKIX in other rare neurological diseases. And we intend to broaden our lifecycle management efforts for this unique product, consistent with our strategy for long-term growth.

And finally, Pillar Three, acquire new assets to expand our portfolio beyond WAKIX. Through the efforts of our dedicated business development team, I am excited that we acquired our first additional asset beyond WAKIX, HBS-102, which is a potential first-in-class molecule with a novel mechanism of action. HBS-102 gives us the opportunity to, once again, lead with the science in narcolepsy and other rare neurological diseases. As you will hear from Dr. Jeff Dayno, we believe that HBS-102, with its unique mechanism of action, potentially represents the next-generation of targeted therapy for narcolepsy beyond those working through histamine and other neurotransmitter systems in the brain, including orexin.

We view this acquisition as another important step on our journey to becoming a leading rare neurological disease company. Our business development strategy is intended to transform Harmony into a multi-product company, with a robust catalyst-rich pipeline of innovative therapies at various stages of development, with the potential for launch both during and after WAKIX life cycle. An important aspect of this strategy is that we're focusing on assets in the rare neurological arena, where we can leverage our existing expertise and infrastructure, enabling us to optimize development and launch, while managing costs, which in turn is intended to create long-term value for our stakeholders. To further support this initiative and the long-term growth of Harmony, we have entered into a strategic collaboration with Blackstone that gives us access to additional capital, while reducing our current cost of capital, and enhances our flexibility so we can continue to invest in our growth strategy. Sandip will speak more about this later in the call.

On that note, I would like to turn the call over to Jeff Dierks, our Chief Commercial Officer. Jeff?

Jeff Dierks

Thanks, John. We saw another strong quarter performance for WAKIX in Q2, as measured by key performance metrics noted on Slide 4. Net revenue for the second quarter was $73.8 million, representing almost a 24% increase from the first quarter 2021. This solid double-digit growth in net revenue was aided by strong prescription demand at the end of the first quarter that helped to drive additional growth in the quarterly average number of patients for Q2, growth in new prescribers of WAKIX, and improvement to gross nets from Q1 that is normal given the impact of seasonal payer dynamics in the first quarter each year.

And moving on to Slide 5, the average number of patients on WAKIX increased 15% from what we reported in Q1, to approximately 3,200 patients. More than two thirds of these patients are refilling WAKIX prescriptions at the highest dose. We anticipate that percentage to increase over time, as more healthcare professionals gain valuable clinical experience with their patients, and see the benefits of the product in treating the debilitating and life-impacting symptoms of excessive daytime sleepiness, or cataplexy. The growth in the average number of patients on WAKIX, demonstrates continued strong demand, despite competitive products entering the market, and also speaks to how the meaningfully differentiated product profile, aligns the unmet needs of the narcolepsy market.

Our strong commercial performance continues to be driven by the following key factors. First, we continue to see broad and meaningful clinical adoption of WAKIX. We saw continued growth in the prescriber base of WAKIX in Q2. Of the more than 8,000 healthcare professionals who treat the majority of the diagnosed narcolepsy patient population, over 38% have prescribed WAKIX since launch through the end of the second quarter. We also continue to see the vast majority of those prescribers becoming repeat writers, with two or more of their narcolepsy patients receiving a prescription for WAKIX since launch. Patient feedback from the community continues to demonstrate positive experience and a strong interest in the product.

Second, the already strong market access for WAKIX, was further strengthened with an increased number of plans making additional positive formulary decision for narcolepsy patients with cataplexy. Over 80% of all US-covered lives have favorable access to WAKIX, and saw recent positive formulary decisions for Type 1 patients within these plans, which helped to take some of the friction out of the managed care workflow approval process. Patient's ability to access to WAKIX, has been accelerated in the second quarter.

Third, we saw improved access to healthcare professionals for our field sales team. ZS Access Monitor data showed that by the end of the second quarter, nearly two thirds of all field sales engagements with healthcare professionals, were in-person, providing more of a meaningful education exchange for branded products and newer products still in launch phase. We saw a corresponding increase in WAKIX topline prescription demand that aligned with the opening of the country, as more healthcare professionals are seeing patients in-person, and more face-to-face interactions are occurring between healthcare professionals and our field sales team.

And lastly, WAKIX offers a meaningfully differentiated product profile. The broad and strong adoption of WAKIX, speaks to the significant unmet need in the narcolepsy market, and how the overall benefit-risk profile of WAKIX aligns to the unmet needs. Despite the growing competitive landscape of products, WAKIX offers a truly unique option for healthcare professionals and patients, as seen on Slide 6. WAKIX offers a first-in-class molecule with a novel MOA, the only product that works through histamine WAKIX is the only non-scheduled treatment option indicated for both excessive daytime sleepiness, or cataplexy, in narcolepsy.

WAKIX use is not a stimulant, with no evidence of drug tolerance or withdrawal symptoms in clinical studies WAKIX can be used as monotherapy or administered concomitantly with other narcolepsy treatments, with no clinically relevant pharmacokinetic interaction with either Modafinil or sodium oxybate, as demonstrated in clinical trials. And WAKIX offers convenient, patient-friendly, once-daily oral tablet administration in the morning upon waking. I am extremely encouraged by our continued strong performance of WAKIX in the narcolepsy market, further reinforcing our perspective that WAKIX offers a unique and meaningful option to treat both excessive daytime sleepiness or cataplexy in adult patients with narcolepsy.

I'll now turn the presentation over to Dr. Jeff Dayno, for an update on our clinical development program. Jeff?

Jeff Dayno

Thanks, Jeff, and good morning, everyone. I'd like to start by speaking to our updated pipeline chart on Slide no. 7. As John mentioned, we have made significant progress on all three pillars of our company growth strategy, specifically with regard to pillar number 2, and our lifecycle management programs for pitolisant. At the end of June, we initiated our Phase 2 clinical trial to evaluate pitolisant in patients with Type 1 myotonic dystrophy, known as DM1. In addition, our Phase 2 trial in patients with Prader-Willi syndrome, or PWS, continues to advance, with patients completing the randomized controlled phase and rolling into the open label extension phase of the trial. Both trials are on track for topline data readout next year.

But the real exciting news for us today is the acquisition of our first product beyond WAKIX, HBS-102, which represents an innovative drug development opportunity that could enable us to potentially bring another new first-in-class therapy to patients living with narcolepsy, and possibly other rare neurological diseases. HBS-102 is a potential first-in-class molecule with a novel mechanism of action that targets melanin-concentrating hormone, known as MCH, neurons in the brain. Scientific evidence suggests that MCH neurons function as the control center and driver of REM sleep and its related behaviors.

Let me start with Slide no. 8, which explains the control center for sleep and wakefulness that are centered in the hypothalamus. The main mediators of wakefulness and sleep/wake state stability, are orexin and hypocretin, produced in the lateral hypothalamus, as well as histamine produced nearby in the tuberomammillary nucleus, or TMN. The main driver of non-rapid eye movement sleep or non REM sleep is GABA, which is produced in the ventral lateral preoptic nucleus or VLPO. And the main generator of REM sleep is melanin-concentrating hormone known as MCH, which is produced in a diffused network of neurons in the lateral hypothalamus interspersed amongst the orexin neurons. Similar to how orexin and histamine neurons drive the wakefulness component of sleep/wake state stability, MCH neurons drive REM sleep and its associated behaviors.

Moving to Slide no. 9, which shows the opposing roles of orexin and MCH related to sleep/wake state function. The panel on the top left depicts how one of the original models of narcolepsy was explained. In an orexin-deficient state that occurs in patients with Type 1 narcolepsy, there is an imbalance between orexin and GABA, such that GABA goes unchecked, which results in sleep intruding into wakefulness that patients experience as excessive daytime sleepiness or EDS. The panel on the top right, depicts a similar kind of imbalance in an orexin-deficient state related to the REM control center, where an imbalance in MCH, causes REM intrusion into wakefulness that patients experience as the symptoms of cataplexy, hallucinations, and sleep paralysis. The figure at the bottom depicts the therapeutic hypothesis for HBS-102. Based on its mechanism of action, working as an MCHR-1 antagonist, HBS-102 will block the activity of the MCH neurons to restore balance between MCH and orexin signaling, decrease REM overdrive, decrease REM intrusions into wakefulness, which will then potentially result in decreased symptoms of cataplexy, hallucinations, and sleep paralysis.

Moving on to Slide no. 10. Preclinical proof of concept of the MCHR-1 mechanism of action, has been established in an orexin knockout mouse model of narcolepsy. This model has good clinical predictability in patients with narcolepsy. This experiment was conducted by Dr. Tom Scammell and his team at Harvard. The graph on the left shows the number of cataplexy attacks, and the one on the right shows the number of short latency transitions into REM sleep, labeled SLREM, which is an electrophysiologic correlate of asleep/wake state instability, and REM intruding into wakefulness. In orexin knockout mice at baseline, those treated with vehicle, had significantly more attacks of cataplexy, and bouts of SLREM, compared to those treated with an MCHR-1 probe molecule, which in this experiment, was SNAP 94847. When the mice were fed chocolate, which excites them and provides a positive emotional stimulus, the number of cataplexy attacks increased, as did the bouts of SLREM, but the MCHR-1 antagonist blocked these events to a similar degree as was seen during the baseline condition.

This preclinical proof of concept data is impressive, and is part of our next steps, which are included on Slide no. 11. We will look to replicate this data with HBS-102 in the erecting knockout mouse model of narcolepsy. In addition, we will work to prepare and submit an investigational new drug application, with the plan to initiate a Phase 2 clinical trial once the I&D is open. We will provide additional updates on the development plan for HBS-102 on future calls. As John stated, this acquisition is an important step in our ongoing mission to become a leading rare neurological disease company, with an innovative product portfolio. Having gained FDA approval for one first-in-class product with a novel mechanism of action, we now have the opportunity to once again, lead with the science, and develop a second first-in-class molecule with a novel MOA for patients living with narcolepsy. This is consistent with our commitment to advancing breakthrough science and addressing true unmet medical needs in patients living with rare neurological diseases. My team and I are excited to go to work on the HBS-102 development program.

With that, I will now turn the presentation over to Sandip Kapadia to review our financials. Sandip?

Sandip Kapadia

Thank you, Jeff, and good morning, everyone. This morning, we announced our strategic financing collaboration with Blackstone, and issued our second quarter 2021 press release, and filed our 10-Q, where you can find the details of our financial and operating results. So, let's start with the strategic financing collaboration with Blackstone, which includes $330 million of capital, as seen on Slide no 12. As you may know, Blackstone is a premier global investment firm with strong transactional experience in providing capital to life science companies, to help further develop, expand commercialize their portfolio.

This transaction is meaningful to Harmony, as it provides up to $200 million of debt capital to pay off our existing loan at a considerably lower interest rate, which will result in an annual interest savings of approximately $10 million. In addition, Blackstone will also provide up to $100 million in capital as we look to expand our pipeline by acquiring and licensing products beyond WAKIX and HBS-102. And finally, this financing also includes a $30 million equity investment in Harmony common stock. We're thrilled that such a fund as Blackstone has chosen to collaborate with us to support our future growth.

So, moving on to our second quarter performance on Slides 13 and 14. In the second quarter, we again posted our highest quarterly net revenues to date, with effectively managing our investment, and posted our second consecutive quarter with positive net income and earnings per share. I'm pleased with the continued momentum we're seeing. For the second quarter of 2021, we reported $73.8 million in WAKIX net product revenue, as compared to $38 million in the prior year quarter. This represents a growth of 94.2%. As Jeff pointed out earlier, this is also a 23.7% increase from Q1 2021, where we had $59.7 million in revenue. We're pleased to see the continued growth in the average number of patient and the number of healthcare prescribers.

The second quarter 2021 gross margin was $61.1 million versus $31.5 million in the prior year quarter. For the second quarter, operating expenses reached $37.8 million versus the prior quarter of $24.2 million. The growth in operating expenses resulted from our continued commercialization of WAKIX and the advancement of our pipeline programs. As a result, we posted second quarter 2021 net income of $14.1 million, or $0.24 per diluted share. This compares favorably to a net loss of $10.5 million, or a loss of $1.34 per share in the prior year quarter.

The underlying operating profitability improved as well. We posted second quarter, non-GAAP adjusted net income of $31.9 million or $0.54 per share versus the prior year quarter net loss of $0.5 million or $0.07 per share. Non-GAAP adjusted net income excludes interest expense, amortization, depreciation, stock-based compensation, and other non-operating items. Non-GAAP adjusted net income is a non-GAAP financial measure. Please see our press release for a reconciliation of this measure.

We also ended the second quarter in a strong cash position, with $159.7 million in cash, up sequentially from Q1. As we look forward to the second half of 2021, we anticipate continued quarter-over-quarter growth in revenue, with normal seasonality during the summer period, as well as increase in investment for R&D and SG&A. we believe the WAKIX launch has been quite successful to date, and we're focused on driving continued WAKIX growth, as well as expand into additional indications that address rare neurological diseases.

We're also very excited about the acquisition of HBS-102. We've been able to be financially prudent in acquiring this early stage asset, with a minimal upfront and success-based future milestones. This approach allows us to maintain a strong cash position, while focusing resources on advancing clinical programs. In the future, assuming success, we'll be obliged to make development, regulatory, sales milestone payments, in addition to tiered royalty in the single to low double-digit range. As an early asset, we expect nominal increases in our R&D until we advanced HBS-102 in the later stage of clinical development.

So, in conclusion, we're operating from a position of strength, as we have a solid balance sheet, access to additional capital, growing revenues, and expanding product pipeline, prudent expense control, and opportunity to expand in rare neurological diseases. As we continue to generate revenues and maintain profitability of the WAKIX franchise, we will look forward to reinvesting this capital to fund our ongoing development program and acquire additional assets.

So, with that, I'd like to turn the call back to John for his closing remarks. John.

John Jacobs

Thank you, Sandip, and thanks to the entire Harmony team. Harmony is delivering on all three pillars of our growth strategy, and with the success of this most recent quarter, we've taken another crucial step forward on our journey to become a leading rare neurological disease company with an innovative pipeline of products. I'm excited about the potential we are building to deliver even more hope and life-changing results to patients in the future.

In summary, the second quarter 2021 represented our sixth consecutive quarter of sequential earnings growth, and our second sequential quarter of profitability. Our development pipeline continues to grow and expand. In addition to our Phase 2 Prader-Willi trial, we initiated a Phase 2 trial in myotonic dystrophy with WAKIX, and acquired the rights to HBS-102, a novel first-in-class molecule. In addition, we have further strengthened our balance sheet and enhanced our flexibility to execute on Pillar Three of our growth strategy, by gaining access to additional financing through the Blackstone collaboration.

Operator, we will now open the call to questions from the audience. Thank you.

Question-and-Answer Session

Operator

[Operator Instructions] Our first question comes from Chris Howerton with Jefferies.

Chris Howerton

Excellent. Congratulations on the great progress this quarter to you, John, and the team.

John Jacobs

Thank you, Chris. Thank you for joining our call.

Chris Howerton

Of course. All right. So, I guess, maybe just a couple of questions from me, and congratulations also on the acquisition of 102. It's really interesting. But first, maybe on the commercial side perhaps for Jeff Dierks, could you give us some color on what you're seeing currently on patients on free drug or the patient assistance programs that you've described in previous quarters, and just kind of maybe what you're seeing relative to what you observed previously there. And then the second question I have is perhaps related to the other Jeff for 102. I just—I guess I'm curious how you're seeing the unmet needs specifically for the REM-related symptoms, such as hallucination, cataplexy, and sleep paralysis, and kind of what segmentation of the narcolepsy market do you see that serving? Thank you.

John Jacobs

Thank you, Chris. Go ahead, Jeff Dierks. Why don't you to take the first question?

Jeff Dierks

Sure. Thanks for the question, Chris. So, as you know, as we've stated before, throughout the pandemic, we have seen an increased demand for our patient assistance program, and that elevated demand has been relatively consistent, even into the second quarter of 2021, where the COVID limitations had started to subside. That's difficult to speculate as to when there'll be less reliance on the patient assistance program as the country continues to deal sort of with the ongoing challenges of COVID. But I think, you know, the important key takeaway here is that even with this elevated demand, we've been able to demonstrate strong net revenue growth and continue to see that strong underlying organic demand for WAKIX, giving us continued confidence in long-term growth outlook for the brand.

Chris Howerton

Cool. Okay.

John Jacobs

Go ahead, Dr. Dayno. Why don't you take the second?

Jeff Dayno

Sure. Yes. Good morning, Chris. Thanks for your question. So, with regards to HBS-102, and the target of REM dysregulation in general, as you know, cataplexy is the most common of those symptoms with regard to random dysregulation and REM intrusion into wakefulness. But the potential for a specific therapy target at all of the symptoms, so the combination of cataplexy, as well as sleep paralysis and hallucinations, will cause the variability of those symptoms in the patient population with narcolepsy. So, we feel that a potential new therapy with that specific mechanism targeting REM dysregulation in general, would have significant potential significant value and utility.

Chris Howerton

Okay. Yes. And I guess, I mean, if maybe if I could just ask for a clarification. So, I guess Jeff, would you view this as an adjunctive therapy to maybe existing therapies that a patient is managed on, or would this be sufficient as a monotherapy in a certain amount of patients?

Jeff Dayno

So, Chris, in addition to the proposed mechanism, in the development program, we're also going to evaluate with regards to the overall potential effect on sleep-wake state stability, and the imbalance between the orexin signaling and the MCH neurons. We're going to assess it also for the ability to stabilize wakefulness and potential to improve EDS as well. So, as we build out the development program, we're looking at both utility and effectiveness for REM dysregulation and the potential also to stabilize wakefulness and address EDS. So, I think that is the potential opportunity, either as a monotherapy or potentially as concomitant therapy with other treatments.

John Jacobs

Well said, Dr. Dayno. It's John, Chris. One of the things we all know about the narcolepsy market is it is a polypharmacy market, and there's significant level of unmet need and complexity with this disease in these patients. And having a unique mechanism of action that comes at this condition from a completely different target than anything else on the market, could facilitate polypharmacy utilization there and be a benefit to patients on top of existing therapies, whether they be branded or generic.

Chris Howerton

Yes. Very good. Well, thanks for all the color and very excited to see the progress there. Thanks.

Operator

Our next question comes from Graig Suvannavejh with Goldman Sachs.

Graig Suvannavejh

Hey, good morning team. Thanks so much for taking my questions, and congrats on the quarter. Maybe if I could ask a forward-looking question for some of my commercial stage companies. They've made some proactive comments on how they're monitoring COVID and the evolving Delta variant. Could you provide any color on how you are thinking about whether it's moving from second quarter into third quarter and perhaps just overall comments on what you're seeing about the second half, or how you're feeling about the second half? And so, that's my first question. I probably have 17 questions, but let me—I won't ask 17, but let me ask that first one. Thanks.

John Jacobs

We'll take them one at a time, Graig, if that's helpful. So, why don't—with the first one, I mean, obviously, Harmony has shown our ability to execute on the launch and commercialization of WAKIX, despite facing immense headwinds, as all of our colleagues and patients, families, and coworkers experienced the last year and into the beginning of this year. And as COVID started to lift, there's a direct correlation with that lift and the opening of offices, foot traffic, increasing the patients into those offices, and therefore potential uptake of prescriptions, including WAKIX. And I think you saw some of that momentum here in Q2 with our strong results. It's hard to predict what might happen with COVID, but let me hand it over to Jeff Dierks. And Jeff, if you wanted to add some commentary to that and what we're thinking about the second half.

Jeff Dierks

Yes. Sure, John, and thanks for the question, Graig. And yes, to reiterate what John shared, in the second quarter, we did see more physician offices opening. We had greater in-person educational engagement from our field sales team, more patients coming back into the office for in-person medication management visits. And there certainly is a correlation in terms of the increase in the WAKIX topline prescription demand that we saw in Q2 aligning with the opening of the country. And I think that speaks to the unmet medical need that we talk about, and really how the meaningfully differentiated product profile of WAKIX aligns to that need.

And as John shared, we're seeing strong momentum in our business. We see a very strong underlying organic prescription demand. I think it's very difficult to speculate forward-looking, Graig, with respect to the impact of the COVID resurgence, or the summer seasonality on the industry of WAKIX, and the exact growth rates that we're going to see moving forward. But I will reiterate that we're extremely encouraged by the continuing underlying strong demand that we're seeing, the strong performance of WAKIX. And we do expect to continue to grow quarter-over-quarter, as we've demonstrated growing through the pandemic previously.

John Jacobs

Yes. And perhaps, Sandip Kapadia, our CFO, Sandip, did you want to add some additional color to that?

Sandip Kapadia

Sure. I think just in addition to what Jeff said, we anticipate continued quarter-over-quarter growth for the second half of the year. Obviously, there's general summer seasonality that typically happens as well. But generally, we feel good about the trends that we're seeing, especially a very strong Q2 that'll certainly carry forward for the balance of the year.

John Jacobs

Thank you Sandip.

Graig Suvannavejh

Maybe as a follow-up. I've heard you discuss or bring up the summer seasonality phenomenon. And I'm wondering, historically speaking, maybe because I'm losing brain cells these days, like, I don't remember how summer seasonality might have either impacted WAKIX last year, although you were much earlier in your launch, or what you've seen historically given the management team's prior experience with these types of products during summertime.

John Jacobs

Good question, Graig. As you know, last year was an unusual year with COVID. It was also our first year of launch. So, unfortunately, we didn't have several years of history prior to that to be able to give you something to anchor that upon. And we believe last year was skewed due to COVID. So, it's really hard to say. Jeff Dierks, anything to add to that, or Sandip?

Jeff Dierks

Yes, I would just say overall, Graig, in any given calendar year, there is seasonality. In the first quarter, there's usually the seasonal para-dynamics that occur and put pressure on gross to nets and the reauthorization of prescriptions. Second quarter is usually followed with strong uptake. Third quarter, you see that traditionally people are taking vacations, right? There's fewer representative and healthcare professional interactions, fewer patient visits to the office.

And then that’s followed usually by a strong fourth quarter, patients filling their prescriptions before the end of the year and their insurance changes. You’ve got pharmacies looking to make sure they’ve got adequate stock and supply for the holidays. So, we’re anticipating to have an element of that industry phenomenon with Q3. But again, it’s very difficult to speculate. We see very strong underlying organic demand. We’re very confident in our continued growth in the average number of patients and net revenues Sandip talked about.

John Jacobs

Thank you, Jeff.

Graig Suvannavejh

Thanks for that color. Maybe if I could ask you a question about the Blackstone deal. Certainly, the size of the deal is noticeable, and it’s great that you can swap out, I guess, in effect more expensive debts for cheaper debt, but in terms of—you’re already profitable. You’re generating good cash flows and certainly building to the balance sheet. And in the context of the BD transaction you announced yesterday, which I have a follow-up question on, how should we be thinking about kind of how that war chest that you’re amassing in terms of cash, how you plan to use that? Is it really more with an eye on funding the trials that you have ongoing, or should we be thinking that that is really perhaps a sign of things to come in terms of increased BD activity, whether it’s the number of deals or the size of the deals?

John Jacobs

So, Graig as you stated, we’re in a strong cash position, about $160 million in cash and cash equivalents on hand, strong balance sheet and generating positive revenue. We do see the recent arrangement with Blackstone, does provide us with additional flexibility to potentially enable execution on a broader range of deals, business development deals that align with our strategic criteria and are a key component of our three-pillar growth strategy. And just as a reminder, that strategy includes the continued growth of WAKIX, and commercialization of WAKIX, the expansion of utility of WAKIX beyond narcolepsy into new indications, and the acquisition of additional rare neurology-focused assets so we can build a rich and innovative pipeline, and especially a pipeline with assets that could launch at different stages, from during WAKIX lifecycle to after. And importantly, Graig, we have the capabilities on our team. We built Harmony with a focus in rare neurology, and our intention is to transform Harmony into a leading rare neuro company with a robust and innovative pipeline. That is our intention, and the arrangement with Blackstone helps to give us additional flexibility to head down that strategic pathway with hopeful success.

Graig Suvannavejh

Great. Thank you for that. And one last question, broad area of questions, I guess, has to do with HBS-102. An interesting asset and an interesting mechanism of action. I think historically, industry has looked at this asset for perhaps the past couple of decades with efforts initially in the obesity space. So, with that in mind, can you give a sense of whether your interest in narcolepsy is relatively new and kind of innovative? Because I don't think I've seen much in the literature on this mechanism necessarily vis-a-vis the interest by industry on the obesity side.

And then secondly, just as it relates to the compound itself, I think this class of compounds has been—have seemed to have troubles finding a therapeutic window or therapeutic margin. I think the issue has been increased potential cardiovascular risk due to either binding activity or QTC prolongation. So, I'm just curious if you've characterized HBS-102 for these types of issues and how confident you feel about the overall profile of the asset. Thanks.

John Jacobs

Graig, two part question. Dr. Dayno will help address that, but we're excited about the emerging science around this target and this compound as it relates to sleep and REM behavioral disorder and narcolepsy, as Dr. Dayno stated in his opening comments. But I'll pass it over to Dr. Dayno to address your questions in more depth.

Jeff Dayno

Yes. Sure, John. Yes. Good morning, Graig. So, we're actually, we're really excited about this asset, as John alluded to, the emerging science with regards to the MCH neurons and that mechanism of action. And as you said, the original focus around obesity and hypothalamic mediate obesity, but as the science evolves and some significant work, as I mentioned, done by Tom Scammell and his group at Harvard, it really pointed to the role of the MCH neurons in terms of the generator and the control center of REM sleep. So, with that, going back about four or five years ago, a lot of the focus shifted, and Tom Scammell and his lab worked on that mechanism, and demonstrated with the MCH Receptor-1 antagonist probe molecule, the significant effect in reducing cataplexy in the orexin knockout mouse model.

So with that, the focus sort of shifted, and that's what kind of got our attention. And realizing some of the recent focus on the orexin agonist, this really represents the potential next-generation therapy in patients with narcolepsy, specifically around REM dysregulation. And as I mentioned before, in our development program, in addition to that, we intend to explore it for stabilizing wakefulness as potential monotherapy, or as one type of treatment in a polypharmacy approach.

With regards to this molecule, and what you mentioned in terms of some of the safety issues, the nonclinical toxicology in the work that's been conducted, has not shown any significant safety signals to date. And we also have some Phase 1 PK data that's been generated actually ex-US in the UK, showing that PK profile. So, we've got a lot of information to work with to start to prepare an IND and submit that, to then open an IND. And the plan is to then go into Phase 2 trials.

Graig Suvannavejh

Okay. Thank you very much. Congrats again on all the progress.

Jeff Dayno

Sure.

John Jacobs

Thank you.

Operator

[Operator instructions] Our next question comes from David Amsellem with Piper Sandler.

David Amsellem

Hey, thanks. I had a few. First, can you comment on patient attrition for WAKIX. I think in the past, you've stated that the range in narcolepsy is about 30% to 50%. Where is that trending for WAKIX? And, assuming greater societal normalization, Delta variant notwithstanding, where do you see that attrition rate settling out? So, that's number one. Number two, can you talk about the mix of patients who are taking WAKIX in combination with an oxybate product? What percentage of overall patients is that are you seeing more combination use with oxybate? Third, as the market becomes more varied, particularly as we get to authorized generics and eventually vanilla generics of sodium oxybate, do you think you'll need to contract more aggressively with payers or recalibrate your payer strategy in any way? Just talk about over the long-term, how you expect to manage the payer dynamics? So, I just want to go through those three and then I have a follow-up. Thanks.

John Jacobs

Okay, David. So, all three apply to commercial. So Jeff Dierks, did you want to take the first question on attrition rate?

Jeff Dierks

Sure. Yes. Thanks, David. So with respect to discontinuation rate compliance and persistency rates, so as you shared, in previous calls we have looked at publicly available data, which suggests that the discontinuation rate of drugs in this category tends to range between 30% and 50%, with compliance rates in the industry usually around 80% to 90%. And what we're seeing is that WAKIX is falling within that range, and it's been relatively consistent with other products in the category. Some of the research that we've done with patients and with healthcare professionals is that the physicians that we've surveyed, believe that WAKIX has a lower discontinuation rate or a low discontinuation rate relative to other narcolepsy treatments. From the patient perspective, we're seeing about 90% of those patients on WAKIX expecting to continue to take the product. So, very strong persistency rates. Discontinuation rates, very consistent with where we're seeing in the category.

Now, again, it's still early in our launch. We're not even two years into commercial. So, we're still going to obviously be observing that patient medication behavior moving forward. And again, I don't want to speculate in terms of what the impact of COVID may or may not be on the discontinuation rate, but I think the overall takeaway is, patient receptivity seems to be very strong. We're getting very positive feedback from the patient community. The perceptions of healthcare professionals is that WAKIX is well within the norm and at the lower end of their patient medication behavior. And we're getting really positive feedback from the community.

John Jacobs

No. Thank you, Jeff. And I believe the next question from David, what—the mix with sodium oxybate, how often is WAKIX used in combination, David, if I understood you correctly.

David Amsellem

Yes.

Jeff Dierks

Yes. So, with respect to source of business, we've talked a lot about the opportunity with WAKIX as being a novel MOA and having the ability to be used as monotherapy or concomitantly with all narcolepsy treatment options. And that's what we see in a polypharmacy type of category, is that WAKIX is being used as monotherapy, and being used in clinical practice in combination with all other FDA-approved narcolepsy medication. With respect to the use of WAKIX and sodium oxybate, there's, you know, a small percentage of patients are using both. We haven't disclosed the exact figure, but if you're thinking about in the low teens is probably where we're looking. And the important thing is that from a payer dynamic, we're not seeing any plans providing any pushback or feedback. This is a very small patient population. There's a small cohort of patients that may require this combination to treat the very debilitating and life-altering symptoms of narcolepsy. So, hopefully that helps give you a little bit of color in terms of the patient disposition of WAKIX.

John Jacobs

And Jeff, you mentioned our unique mechanism of action for WAKIX as the only histamine medication in the market for narcolepsy. And we anticipate it to remain so for quite some time. So, as new products come in or genericizations occur of existing MOA therapies, we believe, and we're optimistic, that WAKIX stands alone in its ability to be unique and differentiated. And that there's more pressure on products with the same mechanism of action when you start to see generics in general as a market generalization. And we're optimistic that WAKIX's unique MOA will help us to remain differentiated for the long run.

Jeff Dierks

Correct. Yes. And David, I know your last question was with respect to just introduction of new products and authorized generic or generic versions of sodium oxybate and potential impacts on contracting. So, what I would say to that is, we continue to be extremely pleased with our strong performance of WAKIX, even with the introduction and availability of other competitive products today. And those are both branded and generic. And we do believe that we are growing the branded segment of the market by offering a meaningfully differentiated product profile that aligns to that unmet need. The overall benefit/risk profile of WAKIX makes it appropriate for the vast majority of patients, and available for the entire narcolepsy prescribing healthcare professional universe due to its non-scheduled status, as John talked about. This threshold to treat makes it available for the broad audience to prescribe. And we believe this strong underlying demand that we see with WAKIX will continue and support our ongoing patient and net revenue growth, even with new competitive entry, both branded and generic coming to the market. And it really supports our belief in the long-term growth opportunity for WAKIX.

David Amsellem

Okay. that's helpful. And if I may just ask a question about biz dev with the financing agreement in place. Just drilling down, what's your appetite for the addition of a commercial stage or market-ready asset, where you can leverage the sales infrastructure you have in place, or even just the late-stage assets where presumably you'd be paying significant dollars upfront? What's your strategic calculus regarding those types of assets?

John Jacobs

David, as I said before, our BD strategy is focused on transforming Harmony to a leading rare neuro company with a robust and innovative pipeline of assets. And we have the capabilities internally, whether it's clinical, regulatory, commercial, to develop and launch drugs like that with success. And we're looking to go rapidly in our search. We have the capabilities to take any asset from early stage all the way through to late-stage and on market. And as we stated earlier, we have a—we're in a strong cash position. We've got a good balance sheet. We're growing revenues. We have access to the public market, and we have our new arrangement with Blackstone, which gives us additional optionality and flexibility. And we don't need to buy a revenue stream in the short run because of that strength. But certainly, we are assessing with an open mind assets, anywhere from early stage, all the way to on-market, as long as they meet our filters and help us achieve that business strategy. So what we're most excited about is our additional optionality and flexibility with Blackstone, our strong performance right now that further fuels our ability to execute on our growth strategy.

David Amsellem

Okay. All right. Thanks guys.

John Jacobs

Thank you, David.

Operator

That concludes today's question-and-answer session. I'd like to turn the call back to John Jacobs for closing remarks.

John Jacobs

Thank you very much. Look, everyone, I want to thank everyone for joining us sincerely. And since we appear to be at the end of the call, I would say, for everyone who joined, we appreciate your energy. We appreciate your questions, and we're so excited that you're on this journey with us to discover, develop, acquire, and provide solutions for patients who are living with and facing orphan and rare neurological disorders. Thank you so much, everyone. We appreciate your time.

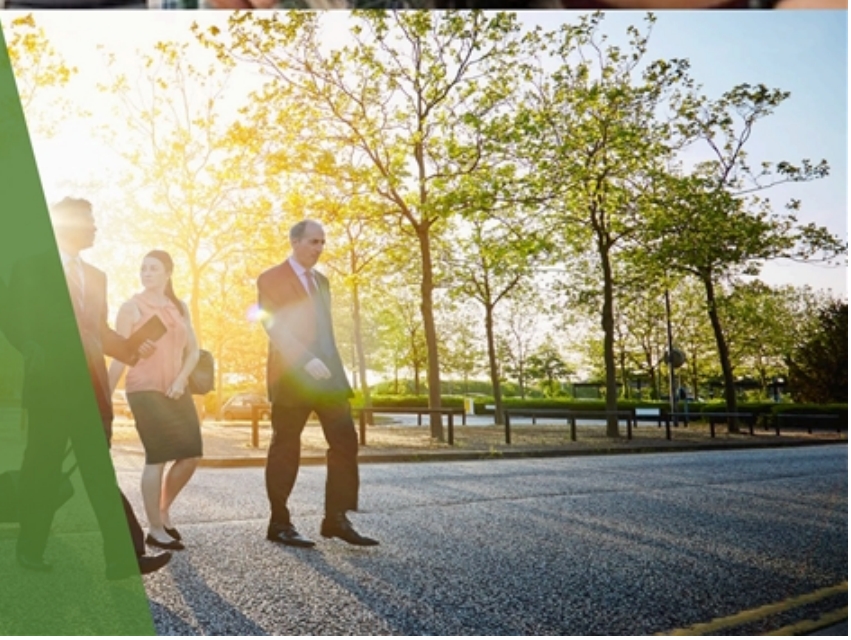
Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.

Exhibit 99.2

HARMONY BIOSCIENCES

Harmony Biosciences Q2 2021 Financial and Business Update



August 10, 2021

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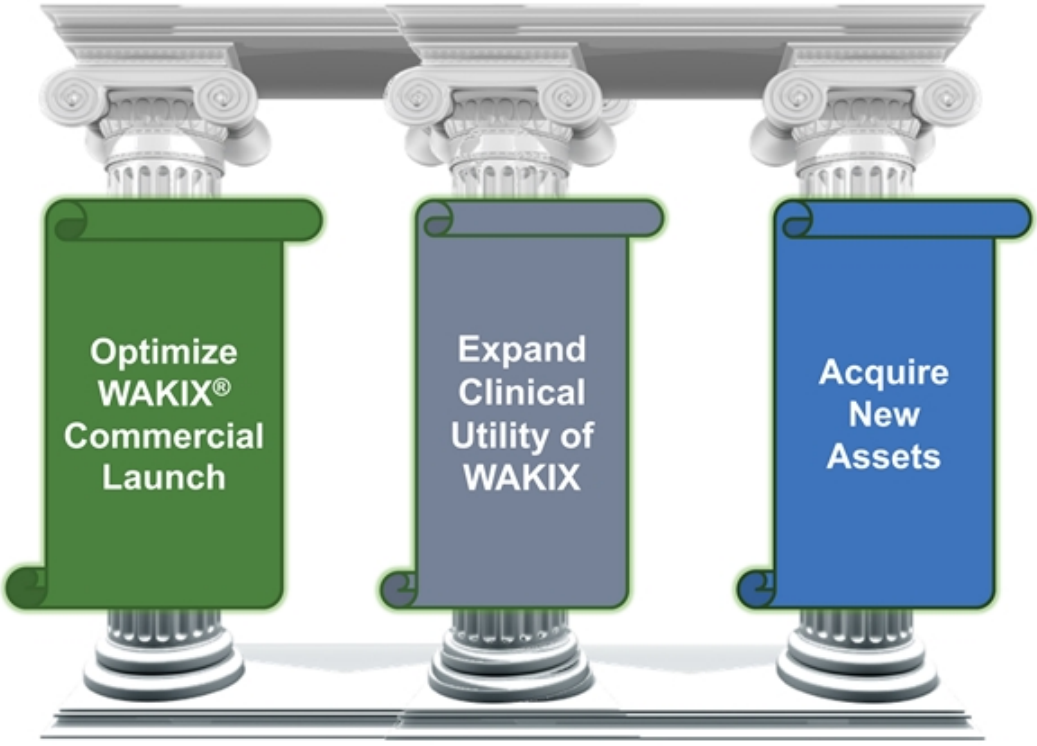
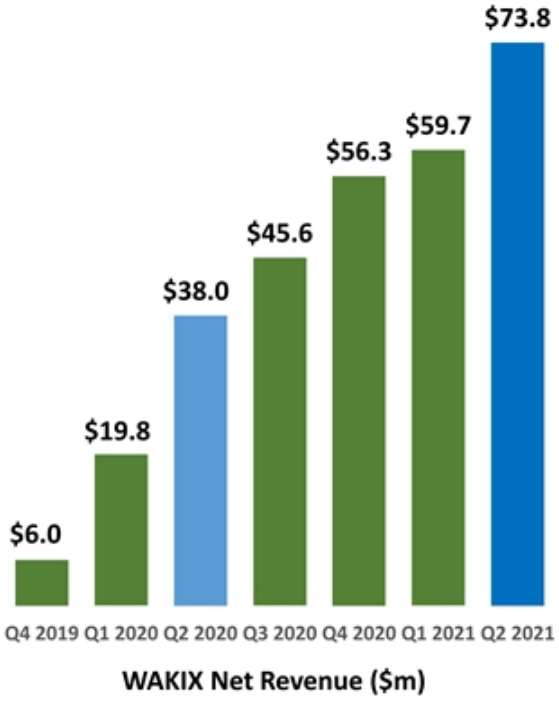
Harmony's Strategy for Growth



Q2 2021 WAKIX Revenue Performance

Continued Growth with Q2 Revenue of $73.8M



2Q20	1Q21	2Q21	2Q21 vs. 1Q21	2Q21 vs. 2Q20
$38.0	$59.7	$73.8	23.6%	94%

Strong Revenue Growth in Q2 2021

- 23.6% growth Q2 2021 vs. Q1 2021
- Over 90% growth Q2 2021 vs. Q2 2020
- Continued sequential quarter over quarter growth from launch

Driving Growth Through Our Launch For WAKIX
Q2 2021 Performance

Wakix pitolisant tablets

Increased Access to HCPs

Patient Outreach Programs & Support

~3,200 Average # of WAKIX Patients

Healthcare Professional Educational Initiatives

>37% Of 8,000 unique HCPs have prescribed WAKIX since launch

Managed Care Education & Outreach

~80% U.S. Covered Lives With Formulary Access

Core Attributes of WAKIX Product Profile Align with Existing Unmet Needs in Narcolepsy

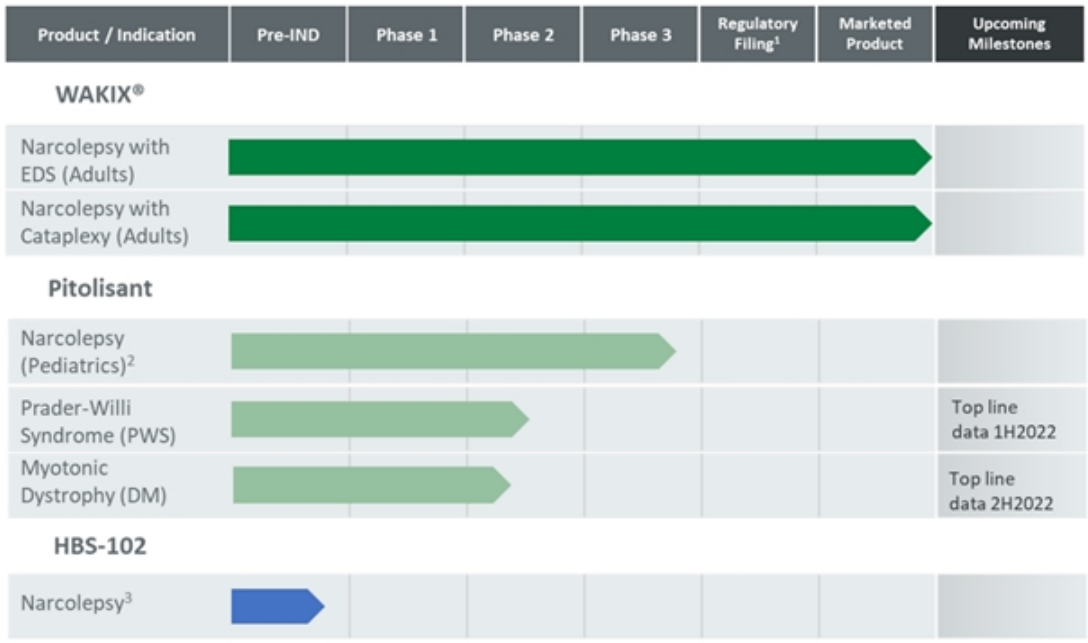
In descending order of importance as stated by combined HCP and patient audience

Top Unmet Needs in Narcolepsy (*cited by patients and HCPs*)	WAKIX (pitolisant)*
Need for non-scheduled treatment options (low/no abuse potential)	First and only FDA approved non-scheduled treatment option for narcolepsy ✓
Need for more tolerable treatment regimens	Established Safety Profile No Boxed Warning, no REMS Program ✓
Need for more effective treatment options	Statistically significant reduction in EDS and cataplexy demonstrated in two Phase III trials ✓
Novel MOAs beyond currently available therapies needed	First-in-class molecule with a novel MOA; H_3R antagonist/inverse agonist; works through histamine ✓
Need for less frequently dosed products; need for once-daily options	Convenient, once daily dosing in the morning upon wakening ✓

* Based on FDA approved product labeling

Source: Harmony ATU, July 2018 (n=286); Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018

Harmony Development Pipeline



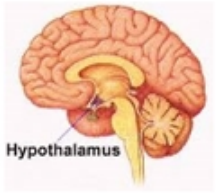
1. Includes New Drug Applications and supplemental New Drug Applications.
2. Current trial being conducted by Bioprojet.
3. Phase 1 PK data available from studies conducted in the UK.

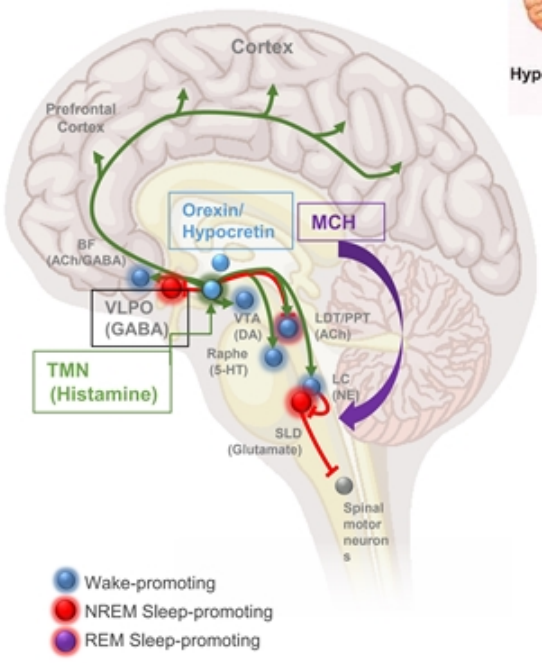
Control Centers for Sleep-Wake Centered in the Hypothalamus (HT)

- Main mediators of wakefulness and sleep/wake state stability:
  - orexin/hypocretin (produced in the lateral HT)
  - histamine (produced in the TMN, also located in the HT)

- Main driver of NREM sleep:
  - GABA (produced in the VLPO in the HT)

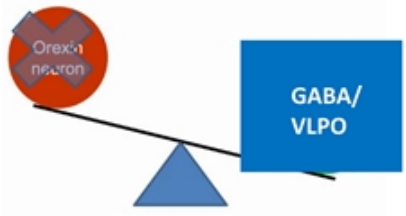
- Main generator of REM sleep:
  - Melanin concentration hormone (MCH) (produced in a diffuse network of neurons in the lateral HT interspersed amongst the orexin neurons)



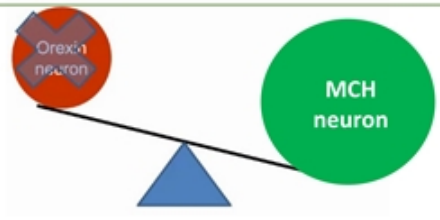


Orexin and MCH: Opposing Roles in the Hypothalamus Related to Sleep-Wake Function

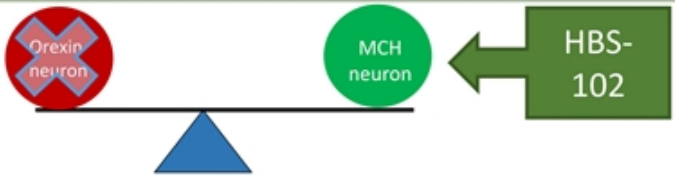
Original model of narcolepsy:
- imbalance between orexin and GABA, the NREM sleep generator
- GABA goes unchecked resulting in sleep intruding into wakefulness (EDS)



In NT1 with orexin deficiency:
- imbalance between orexin and MCH, the REM generator
- MCH goes unchecked causing REM intrusion into wakefulness (cataplexy, hallucinations, sleep paralysis)



HBS-102 therapeutic hypothesis:
- MCH activity goes unchecked in the setting of orexin deficiency (NT1)
- HBS-102, an MCHR1 antagonist, will potentially:
  - restore balance between MCH and orexin signaling
  - decrease REM overdrive → decrease REM intrusions into wakefulness → decrease the symptoms of cataplexy, hallucinations and sleep paralysis

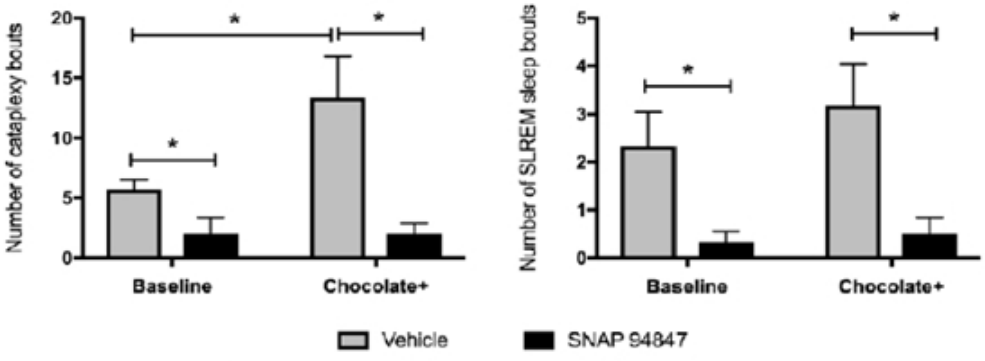


Ferreira, et al, 2017; Gonzalez et al, 2016; Slide adapted from T. Scammell

Pre-clinical POC for MCHR1 Antagonism

Preclinical Evidences

- MCHR-1 antagonist, SNAP 94847, almost completely eliminated cataplexy & SLREM in orexin KO mice[1], a translational cataplexy model.



- MCH neuron activity positively correlated with the number of cataplexy bouts in orexin KO mice[2]

SLREM: short latency transitions into REM sleep (a feature of NT1)

1. Naganuma et al, NeurobiolDis. 2018; 120, 12.
2. Oshio et al. J of NeuroScience. 2013:33;9743.

HBS-102: Next Steps

- Demonstrate preclinical POC with HBS-102 in orexin knockout mouse model
- Prepare IND then submit to FDA
- Initiate Phase 2a proof of concept study once IND opens

Become a leading rare neurological disease company with an innovative product portfolio

Committed to advancing breakthrough science and addressing unmet medical needs

Strategic Financing Collaboration

$330M of financing and growth capital from Blackstone enables Harmony to expand portfolio of assets in rare, neurological diseases

$200M Debt to payoff existing debt facility

$100M Cash available for drawdown within 12 months

$30M Equity investment in common stock

Benefits to Harmony

- Strengthens balance sheet
- Access to additional capital to acquire complementary assets to build our product pipeline
- Lower interest cost - reduces annual interest expense by ~$10M
- Equity investment from premier, global investment firm with leading life sciences capabilities

Q2 2021 Financial Summary *(in millions, USD)*

	Three Months Ended June 30,	
	2021	2020
Net Product Revenues	**$ 73.8**	**$ 38.0**
Cost of Product Sold	12.7	6.4
Total Operating Expenses	**$ 37.8**	**$ 24.2**
R&D Expense	6.5	4.2
S&M Expense	17.0	12.4
G&A Expense	14.3	7.6
Net Income available to common stockholders (Loss)	**$ 14.1**	**$ (10.5)**
Cash & cash equivalents	**$ 159.7**	

Totals may not foot due to rounding

GAAP vs Non-GAAP Reconciliation *(in millions, USD)*

	Three Months Ended June 30,	
	2021	2020
GAAP reported net income (loss)	**$ 14.1**	**$ (0)**
Interest expense / income	7.2	6.9
Taxes	2.0	
Depreciation	0.1	0.1
Amortization	4.6	1.9
EBITDA	28.0	8.9
Stock-based compensation expense	3.8	0.6
Loss on debt extinguishment		
Warrant expense		0.4
Non-GAAP adjusted net income (loss)	31.9	9.9
Accumulation of yield on preferred stock		(10.4)
Non-GAAP adjusted net income (loss) available to common stockholders	$ 31.9	$ (0.5)
GAAP reported net loss per diluted share	**$ 0.24**	**$ (1.34)**
Non-GAAP adjusted net income (loss) per diluted share	$ 0.54	$ (0.07)
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,592,876	7,805,848

Totals may not foot due to rounding


HARMONY
BIOSCIENCES
Thank You
August 10, 2021