July 29, 2025

Alkermes Q2 2025 Earnings Conference Call Prepared Remarks

Sandra Coombs:

Welcome to the Alkermes plc conference call to discuss our financial results and business update for the quarter ended June 30, 2025. With me today are Richard Pops, our CEO, Blair Jackson, our Chief Operating Officer, Todd Nichols, our Chief Commercial Officer, Dr. Craig Hopkinson, our Chief Medical Officer, and Dr. Marcus Yountz, Vice President of Clinical Development.

A slide presentation, along with our press release, related financial tables and reconciliations of the GAAP to non-GAAP financial measures that we'll discuss today, are available on the Investors section of alkermes.com. We believe the non-GAAP financial results, in conjunction with the GAAP results, are useful in understanding the ongoing economics of our business.

Our discussions during this conference call will include forward-looking statements. Actual results could differ materially from these forward-looking statements. Please see slide 2 of the accompanying presentation, our press release issued this morning, and our most recent annual and quarterly reports filed with the SEC, for important risk factors that could cause our actual results to differ materially from those expressed or implied in the forward-looking statements. We undertake no obligation to update or

revise the information provided on this call or in the accompanying presentation as a result of new information or future results or developments.

After our prepared remarks, we will open the call for Q&A, and now I will turn the call over to Richard for some opening remarks.

Richard Pops:

We had a successful second quarter, our commercial and financial performance were strong. And, last week, we took another major step forward in our pursuit of a medicine that has the potential to transform the treatment of narcolepsy.

Now midway through 2025, we are on track to deliver on our key objectives across the business. In commercial, we planned for strong sequential growth and exceeded our expectations in the second quarter. This result was driven by excellent operational execution by a seasoned commercial team. With sustained profitability, no debt and more than $1 billion of cash, we are in a strong financial position with significant optionality.

It is clear to us now that the future growth of the business can be accelerated by the development candidates now in our pipeline. Last week, we reported positive topline results from Vibrance-1, our first phase 2 study of alixorexton, formerly known as ALKS 2680, in narcolepsy type 1.

Vibrance-1 was successful and a critical study in the development of our orexin portfolio -- obviously for the efficacy and safety data it yields, but also for the operational foundation it provides for the phase 3 program.

If you think back to a year ago, we had data from our phase 1b study of alixorexton that suggested robust efficacy and a generally well tolerated profile based on single-day exposures across a range of doses in small cohorts of patients with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia. These data were critical in defining the initial clinical profile and dosing range for alixorexton. This was step one.

Step two is to confirm and extend these observations in multi-week, multi-dose phase 2 outpatient studies. Vibrance-1, in patients with narcolepsy type 1, is the first of these studies. Now, we have randomized, placebo-controlled, six-week, multi-dose data in hand from more than 90 patients with NT1. We've now answered key questions in phase 2 with rigorous assays across larger cohorts of NT1 patients over a longer period of time. These data and insights will be fundamental in preparation for phase 3.

Here are the key findings from this study at the top line. First, the results demonstrated a significant effect on wakefulness and a generally well tolerated profile. This was our pre-test hypothesis and these data were in line with our expectations.

Second, the study provided entirely new and exciting findings relating to fatigue and cognition. These are among the most disruptive symptoms patients with narcolepsy

experience, and they are distinct from excessive daytime sleepiness. In this study, alixorexton showed robust and clear improvements on validated patient-reported measures. Our view is that demonstrating effects in these domains establishes a new standard in the development of orexin 2 receptor agonists in narcolepsy.

These emerging data also further support our hypothesis that the orexin system can be harnessed to address other neuropsychiatric and neurological conditions. We have two additional orexin candidates that we plan to develop for conditions beyond central disorders of hypersomnolence. In Q2, we initiated first-in-human studies for one of these candidates, ALKS 4510. We plan to advance the second candidate, ALKS 7290, into the clinic later this year.

For today, Craig and Marcus will take you through the topline results of the Vibrance-1 study, with significantly more detailed data to be presented at the upcoming World Sleep meeting in September. But first, Blair and Todd will review the financial and commercial performance of the business for the second quarter.

Blair Jackson:

Our second quarter financial results were strong and reflected solid commercial and operational execution. We had planned for accelerated growth from the first quarter and we exceeded our expectations. Financially, the year is progressing nicely and we remain well positioned to achieve our financial guidance for the full year, which we reiterated this morning.

For the second quarter, we generated total revenues of $390.7 million. For our portfolio of proprietary products, we generated net sales of $307.2 million, reflecting 14% year-over-year growth. These results were driven by strong underlying demand, which Todd will address in his remarks, and gross-to-net favorability, primarily related to Medicaid utilization rates and certain other credits during the quarter. These factors drove a one-time GTN benefit of approximately $9 million for VIVITROL and approximately $11 million for ARISTADA. Taken together, these GTN dynamics resulted in a proprietary product revenue tailwind of approximately $20 million in Q2. As we move into the third quarter, we expect Q3 net sales from this portfolio in the range of $280 to $300 million.

Manufacturing and royalty revenues were $83.4 million for the second quarter, including revenues of $39.4 million from VUMERITY and $30.3 million from the long-acting INVEGA products.

Turning to expenses.

Costs of goods sold were $49.5 million, which compared favorably to $61.5 million for Q2 last year, primarily reflecting efficiencies following the sale of our Athlone-based manufacturing business last year.

R&D expenses were $77.4 million, compared to $59.6 million for Q2 last year, reflecting investments in the Vibrance phase 2 studies of alixorexton across narcolepsy and

idiopathic hypersomnia. We expect R&D expense to step up slightly in the second half of the year as we complete our phase 2 studies in narcolepsy and continue to build momentum in our phase 2 study in idiopathic hypersomnia.

SG&A expenses were $170.8 million, compared to $168.1 million for Q2 last year. For trending purposes, we expect SG&A expense to be fairly consistent in Q3 and a modest decrease in the fourth quarter of the year.

This performance generated strong profitability of GAAP net income of $87.1 million, EBITDA of $101.6 million, and Adjusted EBITDA of $126.5 million in the second quarter.

Turning to our balance sheet. We ended the quarter in a strong financial position, with $1.05 billion in cash and total investments. We continue to have $200 million of remaining share repurchase authorization, and going forward, we may opportunistically repurchase shares dependent on market conditions and the capital needs of the business.

As we look ahead, based on our performance during the first half of the year and the expected contribution from our expanded sales efforts, we are on track to deliver record revenues from our portfolio of proprietary products in 2025. As a result of this strong performance, we now anticipate finishing the year toward the higher end of our previously issued financial expectations in terms of both revenues and profitability.

Todd Nichols:

In the second quarter, we recorded net sales from our proprietary product portfolio of $307.2 million, reflecting 14% year-over-year growth. We drove strong end-market demand across VIVITROL, ARISTADA and LYBALVI by executing targeted growth initiatives and delivered strong sequential growth from Q1 to Q2. Due to this demand growth and the gross-to-net favorability during the quarter that Blair outlined, our second quarter proprietary net sales of $307.2 million exceeded the expectations that we provided in May of net sales in the range of $260 to $280 million.

Starting with VIVITROL. Net sales in the second quarter were $121.7 million. VIVITROL performance continues to be driven by growth in the alcohol dependence indication market, and our ability to capitalize on highly localized market dynamics in certain states and payer systems. Looking ahead, we continue to expect VIVITROL net sales for full year 2025 in the range of $440 to $460 million.

Turning to our psychiatry franchise. The expansion of our psychiatry sales force completed earlier this year was an important element of our strategy to maintain a competitive share of voice for LYBALVI and reaccelerate growth for ARISTADA. The early returns from that expansion are encouraging and we are pleased with our progress to date.

For the ARISTADA product family, in the second quarter, net sales were $101.3 million. Leading indicators related to underlying demand were encouraging with increased

prescriber breadth and strong new to brand prescriptions during the quarter. For full year 2025, we continue to expect ARISTADA net sales in the range of $335 to $355 million.

Turning to LYBALVI. Net sales grew 18% year-over-year to $84.3 million. Underlying TRx growth was 22% year-over-year, driven by new patient starts and prescriber breadth. Gross-to-net adjustments were approximately 29% in the second quarter. We now expect gross-to-net adjustments for the full year will be approximately 30%. For the full year, we continue to expect LYBALVI net sales in the range of $320 to $340 million.

Across the portfolio, we are pleased with our second quarter performance and are focused on maintaining this momentum and driving demand in the second half of the year.

Craig Hopkinson:

Last week, we announced positive topline results from the Vibrance-1 phase 2 study of alixorexton in patients with narcolepsy type 1. The data further characterize the clinical profile of alixorexton and demonstrated that once-daily alixorexton normalized wakefulness and excessive daytime sleepiness scores in highly symptomatic patients with narcolepsy type 1 with a generally well tolerated profile across all doses tested. These topline results represent the first of a series of datasets that will emerge from the alixorexton phase 2 program.

The data are extensive and break new ground. We are looking forward to presenting the primary and key secondary endpoints related to wakefulness and cataplexy, and the safety and tolerability profile observed in the six-week, double-blind period of the study in an oral presentation at the upcoming World Sleep meeting at the beginning of September. In addition to the topline results, we will also share data related to the exploratory patient-reported outcomes collected in Vibrance-1, including the fatigue and cognition data outlined in our topline press release last week.

These data are truly exciting, not only in terms of the clinical profile for alixorexton, but also as we plan for additional clinical studies across our portfolio of investigational orexin 2 receptor agonists in disorders where impaired cognitive functioning and fatigue are key clinical features.

Following World Sleep, we expect topline results from Vibrance-2, our phase 2 study in narcolepsy type 2 in the fall. Enrollment in Vibrance-2 is going well and we expect to complete that soon. Topline data from Vibrance-3, our phase 2 study in idiopathic hypersomnia, are expected to follow in mid-2026. Each of these studies provides a significant amount of data to analyze and will deepen our understanding of alixorexton's potential utility across central disorders of hypersomnolence and its differentiating features in the competitive landscape.

In parallel, we are preparing for key regulatory interactions and for the global phase 3 program in narcolepsy that we plan to initiate as rapidly as possible following the topline data from the narcolepsy type 2 study.

Alkermes is at the forefront of development in this exciting potential therapeutic category, and the positive Vibrance-1 data represent an important stride forward for the alixorexton development program and our broader portfolio of orexin 2 receptor agonists.

With that, I'd like to introduce Dr. Marcus Yountz to review the topline data from the Vibrance-1 study. Marcus is Vice President of Clinical Development and the clinical program lead for alixorexton here at Alkermes.

Marcus Yountz:

Vibrance-1 is a six-week, double-blind, placebo-controlled, parallel design study, evaluating three different doses of alixorexton in patients with narcolepsy type 1, or NT1.

The study enrolled a total of 92 patients, with most having moderate to severe disease at baseline. Patients were randomized to one of three once-daily dose levels of alixorexton -- 4, 6, or 8 mg -- or placebo.

The primary endpoint of Vibrance-1 was the change from baseline compared to placebo in the Maintenance of Wakefulness Test, or MWT. MWT is a standardized, quantitative measure of how long patients can stay awake during a 40-minute test period when they're in an environment that is conducive to sleep. These tests are conducted at 2, 4, 6 and 8 hours post-dose. The mean score is calculated by averaging the results of the four tests. While the MWT is less frequently used in real-world clinical settings, it is an important objective endpoint commonly used for regulatory purposes. In Vibrance-1, alixorexton showed dose-dependent, statistically significant and clinically meaningful increases in mean sleep latency at all doses tested at week six. Importantly, all dose groups achieved normative wakefulness, applying the standard convention of a mean sleep latency on the MWT of 20 minutes or more.

The study also evaluated key secondary endpoints, including change from baseline on the Epworth Sleepiness Scale and weekly cataplexy rates compared to placebo.

First, the Epworth Sleepiness scale, or ESS. Unlike the MWT, this scale is widely used in the clinic as a diagnostic tool to assess for excessive daytime sleepiness. ESS is a patient-reported symptom questionnaire asking about the patient's likelihood of falling asleep across eight different scenarios, such as watching TV, riding in a car, or reading a book, over the last week. Higher scores indicate a greater likelihood of falling asleep with a score of 10 and below considered normal. The Epworth scale is useful in that the seven-day look back period provides a holistic view of patients' sleepiness beyond the 8-hour MWT test period. Here, across all doses tested, alixorexton demonstrated

statistically significant and clinically meaningful improvement at week 6, with each dose group achieving normative levels.

In addition to excessive daytime sleepiness, NT1 patients can experience a sudden involuntary loss of muscle tone called cataplexy. Vibrance-1 evaluated mean weekly cataplexy rates. To measure this endpoint, patients are asked to keep diaries of cataplexy events that they experience. The average number of weekly events across weeks 5 and 6 in the alixorexton-treated subjects were then compared to those experienced by the placebo group.

Across all doses tested, alixorexton showed numerical and clinically meaningful improvements in cataplexy compared with placebo. And, on the pre-specified analysis, met the threshold for statistical significance at the 6 mg dose. We are confident in the effects of alixorexton on cataplexy and believe there are learnings here related to our implementation of this assay that we will apply in phase 3 to reduce variability and the impact of outliers. We look forward to sharing additional analyses of these data at World Sleep.

While excessive daytime sleepiness is the hallmark symptom of narcolepsy, many patients also experience other symptoms, such as fatigue and cognitive dysfunction. These can result in significant morbidity as well as impaired quality of life. Our hypothesis has been, given the nature of the neurocircuitry affected, that alixorexton could have an impact on many of the aspects of this disease that affect patients' day-to-

day functioning. The British Columbia Cognitive Complaints Inventory, or BC-CCI, and the PROMIS Fatigue scales capture two of these common and often debilitating effects of narcolepsy.

The BC-CCI evaluates concentration, memory, expressing thoughts, word finding, slow thinking, and difficulty solving problems. The PROMIS-Fatigue measures patients' frequency and intensity of fatigue, along with its impact on physical, mental, and social activities. It's important to note here that fatigue is a symptom that patients experience which is distinct from sleepiness. While sleepiness is a general feeling of being tired and wanting to sleep, fatigue is a broader feeling of exhaustion that can be long-lasting and may not be resolved by sleep.

We also looked at the Narcolepsy Severity Scale. The NSS captures a holistic assessment of disease severity by evaluating five key narcolepsy symptoms: excessive daytime sleepiness, cataplexy, hallucinations, sleep paralysis, and disturbed nighttime sleep.

On each of these exploratory patient-reported outcome scales: the BC-CCI, PROMIS Fatigue and the NSS, alixorexton demonstrated clinically meaningful improvements from baseline compared to placebo that were statistically significant. Of course, the p-values here are nominal due to the exploratory nature of these endpoints.

From a clinical perspective, these results are compelling due to the robustness and, particularly, the consistency – across all doses of alixorexton as well as across various complementary assays. This is the first time that we've seen data from the orexin class on these fatigue and cognition scales. We believe this differentiates alixorexton from other development programs and builds upon the evidence base that orexin 2 receptor agonists with appropriate pharmaceutical properties could have broad potential utility across a range of neurological or neuropsychiatric disorders.

Now I'll turn to safety and tolerability. Overall, alixorexton was generally well tolerated in this study. The majority of the treatment-emergent AEs were mild to moderate in severity, and no treatment emergent serious adverse events were seen. The TEAEs that did occur were generally consistent with the events that we observed across the phase 1 studies in healthy volunteers and in subjects with NT1, NT2, and IH. Among the many clinical safety assessments we conducted in the study, two of particular interest are hepatic labs and ophthalmic exams, and importantly, there were no treatment-emergent safety signals seen in these assessments.

Overall, we are very pleased with the safety and efficacy profile thus far, and we look forward to presenting the datasets at World Sleep.

Richard Pops:

That's a summary of the topline findings. There is a lot more to come, and you'll begin to see it in a few weeks at World Sleep.

These data in NT1 represent a meaningful step forward for the alixorexton development program and provide a substantial new dataset that significantly expands our understanding of orexin biology. Not just relevant to narcolepsy, but its potential across a broad range of neuropsychiatric and neurological disorders.

We are moving forward with confidence and a sense of urgency as we prepare for the initiation of our registrational program in narcolepsy. And with clear findings relating to cognition and fatigue adding to what we have seen for excessive daytime sleepiness, we now have further data supporting development of additional orexin candidates in other disease states beyond sleep disorders.

As you've heard throughout this call, the business is in a strong position. Our commercial team is on track to deliver proprietary product net sales in excess of $1 billion and robust profitability in 2025. Our balance sheet is strong and provides strategic optionality with more than $1 billion in cash. Our pipeline programs are advancing. Alixorexton is the first major potential commercial opportunity to emerge from our orexin portfolio, but we also believe that sleep disorders are just the beginning for this exciting new therapeutic category.