May 1, 2025

Alkermes Q1 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 March 31, 2025. With me today are Richard Pops, our CEO, Todd Nichols, our Chief Commercial Officer, Blair Jackson, our Chief Operating Officer and Dr. Craig Hopkinson, our Chief Medical Officer.

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:

I am going to start by recognizing the passing of our colleague and friend Iain Brown, following a courageous battle with cancer. Known to many of you, Iain represented the best of our company in many ways, through his intellect and professionalism, his kindness and humanity, and his sense of humor. I want to thank all of you who sent along your condolences and remembrances. It meant a lot to us.

As you know, Blair Jackson has been serving in the role of interim principal financial officer since Iain went on medical leave in early 2024. Blair has done an excellent job among his other responsibilities and will continue to serve in that role as we seek to identify Iain's successor.

A few things to cover this morning, so let's dive right in. On today's call, Todd will start with an overview of the performance of our commercial products, Blair will review the financial results for the quarter and provide some insights regarding Alkermes' positioning within the current macroeconomic conditions. And, given the exciting progress we are making across the orexin portfolio, Craig Hopkinson, our head of R&D and CMO, will provide an update. You'll be hearing from him more going forward as we move into a data-rich phase of the ALKS 2680 program.

So here's my perspective on where we stand in May 2025: the summary is that we are well positioned and right on plan. Our first quarter commercial performance was solid and slightly ahead of the expectations that we provided on our last earnings call. Each of our medicines has a differentiated value proposition and we are focused on maximizing the potential of LYBALVI, ARISTADA and VIVITROL in their respective markets. Financially, our first quarter results were on plan and, this morning, we reiterated our financial expectations for the year. Across the commercial and financial elements of our business, we continue to focus on driving growth and profitability.

The exciting new developments are happening in R&D. This will be a pivotal year across the orexin 2 development landscape, and Alkermes is at the forefront of development in this exciting potential therapeutic category. Our ALKS 2680 phase 2 program is designed to generate a substantial dataset that characterizes the efficacy, safety and tolerability of a wide range of doses across narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia. As we had hoped and anticipated, as we activated sites around the world and investigators gained experience with our study, the phase 2 program began to accelerate and is advancing with real momentum.

The NT1 study, Vibrance 1, is now fully enrolled. We expect topline results early in the third quarter. The NT2 study, Vibrance-2, is enrolling well. We expect to complete enrollment mid-year with data to follow in the fall. The results of Vibrance-1 and Vibrance-2 will represent two of the most substantial datasets to be generated in this

therapeutic category to date and will provide important information as we advance the program toward planned phase 3 studies.

We are on the cusp of potentially transformative data and are planning for an exciting second half of the year.

Finally, with respect to the macro environment, Blair will give you some details and I will be happy to answer any questions you may have. But, in summary, we are paying attention to two main topics: Medicaid changes under reconciliation and FDA. With regard to potential tariffs, and foreign reference pricing, we are in an advantageous position because we manufacture all of our proprietary products here in the U.S., in the state of Ohio, and we do not commercialize them in markets outside of the U.S.

Todd Nichols:

In the first quarter, we recorded net sales from our proprietary product portfolio of $244.5 million, slightly above the expectations that we outlined in February, reflecting 5% year-over-year growth driven primarily by LYBALVI.

Starting with VIVITROL. Net sales in the first quarter were $101.0 million. VIVITROL performance continues to be largely driven by the alcohol dependence indication, which is the primary focus of our promotional efforts and currently accounts for approximately 75% of VIVITROL volume. Looking ahead, we continue to expect VIVITROL net sales for 2025 in the range of $440 to $460 million.

For the ARISTADA product family, in the first quarter, net sales were $73.5 million. In 2025, we continue to expect ARISTADA net sales in the range of $335 to $355 million.

Turning to LYBALVI. Net sales grew 23% year-over-year to $70.0 million, primarily driven by underlying TRx growth of 22%, with growth coming from both the schizophrenia and bipolar I disorder indications. As we indicated on our last earnings call, gross-to-net adjustments were approximately 31% in the first quarter, and we expect will remain consistent in the low-to-mid 30% range for the remainder of 2025. For the full year, we continue to expect LYBALVI net sales in the range of $320 to $340 million.

We continue to make strategic investments designed to drive awareness and uptake of our psychiatry franchise products. In the first quarter, we completed the expansion of our psychiatry sales force, which is now fully deployed in the field with a focus on maintaining a competitive share of voice for LYBALVI and reaccelerating growth for ARISTADA. We expect to see tangible contributions from the new sales positions within a few quarters.

Across our proprietary products, inventory at the wholesaler level was drawn down as expected during the first quarter, and is now in a normal range for all three products.

Each of our products offers a unique value proposition in their respective category supported by established efficacy, long-term clinical data and real-world patient experience. We are off to a solid start in 2025 and believe we are well positioned to achieve our financial expectations for the year. We look forward to sharing our progress with you.

Blair:

Our first quarter performance was slightly ahead of our expectations and we remain on track to achieve our financial guidance for the year. Macroeconomic conditions are dynamic and rapidly evolving. We are well positioned with more than $900 million of cash and investments on the balance sheet, a business generating substantial cash flow, significant growth opportunities ahead and the ability to adapt quickly to the environment. We remain focused on executing against our strategic objectives for the year and are preparing for the key data readouts from the ALKS 2680 phase 2 narcolepsy studies later this year.

Before I detail our financial results, I'll provide a brief overview of our position with respect to the macroeconomic policy landscape. Starting with our manufacturing footprint, all of our proprietary products are manufactured at our Ohio facility and are sold exclusively in the U.S. The vast majority of our manufacturing supply chain is also sourced domestically. We import a small amount of active pharmaceutical ingredient from certain suppliers abroad, but this represents less than 5% of our cost of goods sold. Additionally, we maintain significant safety stock of API which, if necessary, could

provide flexibility to adapt our supply chain sourcing without significant disruption. We will continue to carefully monitor the evolving policy environment for any potential impacts to our business, but believe we are in a strong position with our U.S.-based manufacturing and supply chain.

Turning to our financial results for the first quarter, we generated total revenues of $306.5 million, slightly ahead of the expectations we outlined on our fourth quarter call. These results were driven by our proprietary product portfolio which grew 5% year-over-year.

For our portfolio of proprietary products, we generated net sales of $244.5 million. As we move into the second quarter, we expect Q2 net sales from this portfolio in the range of $260 to $280 million.

Manufacturing and royalty revenues were $62.0 million for the first quarter, including revenues of $27.8 million from VUMERITY, $17.7 million from the long-acting INVEGA products and approximately $9 million from RISPERDAL CONSTA.

Turning to expenses.

Costs of goods sold were $49.2 million, compared to $58.6 million for Q1 last year, primarily reflecting efficiencies following the sale of our Athlone-based manufacturing business last year.

R&D expenses were $71.8 million, compared to $67.6 million for Q1 last year. This consisted of focused investments in our neuroscience development programs, primarily related to our ongoing phase 2 studies of ALKS 2680 in narcolepsy type 1 and narcolepsy type 2, as well as the recent initiation of our phase 2 study in idiopathic hypersomnia. We expect R&D expense to increase modestly in the second quarter and remain fairly consistent for the remainder of the year.

SG&A expenses were $171.7 million, compared to $179.7 million for Q1 last year, reflecting the mix of promotional activities supporting our commercial products as we continue to focus on driving efficiency. For trending purposes, we expect SG&A expense in the second quarter to remain fairly consistent with Q1 levels, with a modest step down in the second half of the year.

We continue to focus on driving profitability. In Q1, we generated GAAP net income of $22.5 million, EBITDA of $22.8 million, and Adjusted EBITDA of $45.6 million.
Turning to our balance sheet. We ended the first quarter in a strong financial position, with $916.2 million 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.

The financial performance we delivered in the first quarter was slightly ahead of our expectations and provides a strong foundation to achieve our financial guidance for the year.

Craig Hopkinson:

I'm pleased to join you with an update on the development programs for our orexin 2 receptor agonist portfolio. Our ALKS 2680 program, focusing on central disorders of hypersomnolence, is advancing with strong momentum. Investigators across the phase 2 program are gaining experience in the studies and, with the clinical trial network now largely established, screening and enrollment accelerated significantly in the narcolepsy studies during the first quarter. We look forward to further harnessing that interest and enthusiasm in our idiopathic hypersomnia phase 2 study and for potential phase 3 studies.

At the same time, we are moving forward aggressively to expand our research into new disease areas for orexin 2 receptor agonists. A couple years ago, we initiated Project Saturn, with a goal of advancing new molecules for a broad range of disorders. This year, we plan to start the clinical work underpinning this strategy. The orexin 2 receptor agonist pathway has broad potential applicability, and we are a leader in evaluating the utility of this novel pharmacology.

With that as an introduction, let's start with ALKS 2680. In the phase 1b study we completed last year, ALKS 2680 demonstrated a highly potent clinical profile in the

intended patient populations. In that study, we established initial efficacy, safety, tolerability and dose response profiles across narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia. The key objective of the phase 2 program is to more fully elaborate the dose response curve in larger patient populations, define the lower and upper limits in terms of both efficacy and tolerability and inform dose selection for the planned phase 3 program.

The phase 2 program is well underway. Vibrance-1 is a six-week, double-blind, placebo-controlled, parallel design study in narcolepsy type 1, or NT1. NT1 is defined by an absence of orexin producing neurons in the hypothalamus. People living with NT1 experience both excessive daytime sleepiness and cataplexy, which is a sudden loss of muscle tone. The primary endpoint of Vibrance-1 is the change from baseline in the Maintenance of Wakefulness Test, or MWT. MWT is a quantitative measure of how long patients can stay awake. The study will also evaluate secondary endpoints, including change from baseline in weekly cataplexy rates and change from baseline on the Epworth Sleepiness Scale, which is a patient-reported measure of the patient's situational likelihood of falling asleep.

As clinical trial sites were initiated and gained experience with the studies, investigator interest intensified, and enrollment in Vibrance-1 is now complete. We expect to report topline data from Vibrance-1 early in the third quarter.

Narcolepsy type 2, or NT2, is a more heterogeneous disease compared to NT1. People living with NT2 may have more functional/normal orexin systems, however they still experience excessive daytime sleepiness. Vibrance-2 is an eight-week, double-blind, placebo-controlled, parallel design phase 2 study in NT2. In this study, we plan to evaluate changes from baseline in both MWT and Epworth as dual primary endpoints.

Vibrance-2 will generate the largest dataset to date for an orexin 2 receptor agonist in the NT2 patient population. We have strong momentum in screening and enrollment and expect to complete enrollment midyear and have topline data in the fall.

The most recent development in the ALKS 2680 program is the initiation of Vibrance-3, our phase 2 study in idiopathic hypersomnia. Vibrance-3 is similar to Vibrance-2 in terms of the three doses being studied: 10, 14 and 18 mg, as well as the 8-week duration of the randomized, double-blind, placebo-controlled parallel design. The primary endpoint in this study is change from baseline in the Epworth scale. The study will also evaluate changes in the Idiopathic Hypersomnia Severity Scale as a secondary endpoint. We expect data from this study in mid- 2026.

We are focused on capitalizing on our momentum and preparations for phase 3 studies so that we can move as quickly as possible once we have phase 2 data in hand. We have established a robust clinical trial network with more than 45 sites initiated to support the phase 2 program and expect to be able to leverage this network and clinical relationships to streamline operational study start-up timelines for phase 3. Preparations

for other phase 3 workstreams, including manufacturing of clinical supply, study design planning, and key regulatory interactions, are also underway. We expect to exit phase 2 with strong momentum and are focused on carrying that forward into phase 3.

I'll finish with a quick update on our Project Saturn initiative. Orexin 2 receptor agonists have been shown preclinically to activate neurocircuitry associated with mood, attention, vigilance and cognition. Project Saturn is focused on harnessing these effects in the treatment of other diseases outside of hypersomnolence disorders.

We are on track to advance two additional orexin 2 receptor agonists into first-in-human studies this year. ALKS 4510 will be the first, with single-ascending dose studies expected to commence in the coming weeks. ALKS 7290 is anticipated to follow later this year. These two compounds share certain similarities with ALKS 2680 but will have their own unique pharmacokinetic and pharmaceutical properties. Once the initial pharmaceutical profiles are established in healthy volunteers, we plan to move quickly into disease-relevant studies to establish proof-of-concept in indications of interest.

The spectrum of disorders under consideration ranges from rare neurodegenerative and neurodevelopmental diseases to broader neuropsychiatric disorders, each seeking to harness the orexin system to drive wakefulness, attention, cognition and activate downstream neurocircuitry related to mood and other domains. Our preclinical work is ongoing and continues to support the potential of the orexin pathway.

Alkermes is well positioned as a leader in development in this exciting new therapeutic category in sleep disorders and beyond.

Richard Pops:

Across the business, we are executing against our strategic objectives, focusing on the initiatives that we believe represent our greatest growth opportunities. Let me close with a few thoughts:

First, with respect to the macro landscape. We are well-prepared to operate in this kind of environment. The patient populations that our commercial medicines are indicated for have always demanded a high level of engagement with policymakers and regulators. Our presence and capabilities in these areas become even more important against the backdrop of rapid and significant change. Our focus is on advocating for policies that maintain access to care for our patient populations, interacting with regulators to support continuity of critical regulatory workstreams, and identifying opportunities for efficiency in a thoughtful manner. We have been doing this for a long time, and will continue that work.

Next, irrespective of the political environment, what will continue to drive valuations in our industry is the discovery and development of important new medicines with therapeutic value for patients and long potential patent lives. This is why the orexin development program is so central to our planning. New molecules based on new biology. Our program begins with narcolepsy and ALKS 2680, and has shown potential

to extend beyond that into other exciting neuroscience indications. We have been building this type of valuation potential into the business thoughtfully over the past several years, and we are excited to be on the brink of important new data sets.