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Alkermes Q4 & FY 2024 Earnings Conference Call Prepared Remarks

Sandy Coombs:

Welcome to the Alkermes plc conference call to discuss our financial results and business update for the quarter and year ended December 31, 2024. With me today are Richard Pops, our CEO, Blair Jackson, our Chief Operating Officer and Todd Nichols, our Chief Commercial 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 report 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.

Richard Pops:

2024 was a year defined by commercial execution, efficiency and profitability, and pipeline progress. During the year, key achievements across each of these initiatives demonstrated the realization of our goal of becoming a pure play, highly-profitable, fully integrated neuroscience biopharmaceutical company. This morning, we will review our strong 2024 financial performance, discuss our financial expectations for 2025, and provide our view of the key value creation opportunities for Alkermes in the year ahead.

Blair and Todd will give you the details, but here is my view in the aggregate:
2024 was a banner financial year for the company. We exceeded $1.5 billion in revenue, primarily driven by our proprietary commercial portfolio of medicines discovered, developed, and commercialized by Alkermes. We managed the business to drive robust profitability and met our EBITDA goal. This yielded more than $450 million of EBITDA from continuing operations while investing in the pipeline programs that we believe will drive the future growth of the company.

We used the profits we generated to strengthen the balance sheet -- we repurchased approximately 8 million shares, retired all of our debt and ended the year with $825 million of cash on the balance sheet.

We take the same financial ethos into 2025 and will continue to manage the business with a focus on profitability. As we previously outlined on our last earnings call, we expect to generate over $200 million of EBITDA in 2025, while advancing the orexin program as aggressively as we can. The financial expectations for 2025 that Blair will outline next reflect the line of sight we have into current dynamics, with customers and payers, in the competitive markets where we operate. For our mature products, VIVITROL and ARISTADA, we expect flat to modest growth, and for our most recently launched product, LYBALVI, continued growth and uptake in the market.

We will take you through the specifics, particularly for Q1, so we all can start the year in alignment. As we prepare for key ALKS 2680 phase 2 data readouts later this year, we are focused on delivering solid and predictable financial performance.

All that leads to what we think is the principal value driver for the company in 2025: key data readouts for our lead development candidate, ALKS 2680, which is currently enrolling two well-powered, randomized, placebo-controlled phase 2 studies in patients with narcolepsy. With planned cumulative enrollment of 160 patients and expected completion in the second half of this year, we designed these studies to provide robust datasets that will highlight the key characteristics of this candidate, and, along with that, the commercial opportunity and competitive positioning associated with it. I will provide some additional insights into the ALKS 2680 development program later in the call, but for now the point is that ALKS 2680 is on the threshold of revealing its medical and commercial potential.

We are a leader in the development of new medicines based on orexin biology, which is one of the most exciting potential new therapeutic categories within neuroscience and represents a transformational opportunity for Alkermes in the years ahead.

We have been laying the groundwork for 2025 for several years and we are well positioned heading into an eventful year.

Blair Jackson:

2024 was Alkermes' strongest year of financial and operational performance to date. Financially, we generated more than $1 billion in revenue from our proprietary commercial product portfolio, delivered EBITDA from continuing operations of approximately $452 million, repurchased $200 million of the company's shares, retired $290 million of debt and ended the year debt-free with approximately $825 million of cash on the balance sheet.

Operationally, we completed the sale of our manufacturing business in Ireland, which streamlined our manufacturing footprint and positioned the company to expand gross margins going forward. We also made significant progress advancing our neuroscience development pipeline and are looking forward to important phase 2 data readouts this year for our lead candidate, ALKS 2680, in narcolepsy.

In 2024, we generated total revenues of more than $1.5 billion, driven primarily by our proprietary product portfolio which grew 18% year-over-year and generated more than $1 billion in net sales. For the year, we recorded VIVITROL net sales of $457.3 million, reflecting 14% growth year-over-year. Net sales of the ARISTADA product family increased 6% year-over-year to $346.2 million in 2024; and LYBALVI net sales increased 46% year-over-year to $280.0 million.

Across the proprietary commercial portfolio, due to the timing of shipments ahead of the holidays, the fourth quarter included an extra ordering cycle to cover the first week of the year. Inventory normalized to pre-holiday levels in early January so you can think about this as pulling one week of orders from Q1 into Q4. These dynamics resulted in year-end wholesaler inventory build of approximately $20 million and primarily impacted VIVITROL and ARISTADA. Our fourth quarter results also reflected gross-to-net favorability primarily related to lower Medicaid and VA utilization and certain other credits. These factors drove a one-time GTN benefit of approximately $12 million for VIVITROL and approximately $3 million for ARISTADA. Taken together, these inventory and GTN dynamics resulted in a proprietary product revenue tailwind of approximately $35 million in Q4.

Moving on to our manufacturing and royalty business. For the year, we recorded manufacturing and royalty revenues of $474.1 million, primarily driven by royalties

related to long-acting INVEGA products of $236.4 million and revenues from VUMERITY of $134.0 million.

Now, I'll turn to our full-year 2024 operating expenses and our financial results from continuing operations. These results reflect the separation of our former oncology business which was completed during the fourth quarter of 2023.

Costs of goods sold were $245.3 million, compared to $253.0 million for the prior year.

R&D expenses were $245.3 million, compared to $270.8 million in the prior year. This consisted of focused investments in our neuroscience development programs, primarily related to the ALKS 2680 clinical program and support activities for our proprietary commercial products.

SG&A expenses were $645.2 million, compared to $689.8 million in 2023, as we continued to invest in the growth of LYBALVI and focus on efficiency.

Overall, the business drove significant profitability from continuing operations generating GAAP net income of $372.1 million, non-GAAP net income of $494.4 million, and EBITDA of $452.4 million for the year.

Turning to our balance sheet. We ended the year in a strong financial position. As I outlined earlier, during the fourth quarter, we prepaid approximately $290 million of our outstanding debt, ending the year debt-free with approximately $825 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.

In 2025, we plan to manage the business to deliver significant profitability and cash flow while investing in the growth opportunities that we believe will be the key drivers of shareholder value. During our third quarter earnings call, we previewed our expectation to generate EBITDA of greater than $200 million for 2025 and today I'll provide more detailed financial expectations. In addition, given the transformation of our business over the last several years and feedback we have received from shareholders, we are transitioning to an Adjusted EBITDA metric going forward in lieu of non-GAAP net income, as we believe Adjusted EBITDA better captures the dynamics of our underlying business. Our expectations were outlined in the press release and 8-K issued this morning.

Starting with the topline, we expect total revenues for 2025 to be in the range of $1.34 to $1.43 billion, driven primarily by net sales from our proprietary products in the range of $1.09 to $1.15 billion. As we've previously disclosed, in 2025, we expect manufacturing and royalty revenues to decrease by approximately $215 million compared to 2024 reflecting the expiration of the INVEGA SUSTENNA U.S. royalty in

August 2024 and the conclusion of certain legacy manufacturing revenues following the sale of our manufacturing business in Ireland last year.

Turning to expenses. Costs of goods sold are expected to be in the range of $185 to $205 million, reflecting our streamlined manufacturing footprint.

R&D expenses are expected to be in the range of $305 to $335 million. This level of R&D spend is to accommodate our ongoing ALKS 2680 phase 2 programs in narcolepsy and the planned initiations of the ALKS 2680 phase 2 program in IH and first in human studies for ALKS 4510 and ALKS 7290, our next orexin 2 receptor agonist candidates.

SG&A expenses are expected to be in the range of $655 to $685 million, which reflects investments in the expansion of our psychiatry sales team, targeted investments in the promotional support for our commercial products and continued focus on operational efficiency.

We expect an effective tax rate of approximately 17% in 2025.

We are committed to maintaining a robust cash generating business and expect to deliver GAAP net income in the range of $175 to $205 million, EBITDA in the range of $215 to $245 million and Adjusted EBITDA in the range of $310 to $340 million.

As we look ahead to Q1, due to more pronounced seasonality related to year-end ordering patterns in Q4 and the dynamics within our royalty and manufacturing portfolio that I previously outlined, I'll provide some additional color on quarterly trending expectations to facilitate modeling.

In the first quarter of 2025, we expect net sales from our proprietary commercial product portfolio to be in the range of $220 to $240 million. This reflects our expectation of wholesaler inventory normalization related to the extra order cycle in Q4 and usual first quarter inventory drawdown patterns, typical Q1 patient copay and deductible reset dynamics, and historical demand patterns.

The royalty and manufacturing revenue will reflect the annual reset of the royalty tiers on the remaining long-acting Invega products, the conclusion of certain manufacturing revenue streams, and typical Q1 end-market seasonality. We expect these factors will drive a sequential decrease of approximately $60 million compared to Q4.

On the expense side, we expect costs of goods sold in the first quarter of 2025 to be down sequentially from the fourth quarter, consistent with historical Q1 sales patterns. For the first quarter of 2025, we expect R&D expenses to increase approximately $15 million sequentially from Q4, primarily driven by activities related to the ALKS 2680 phase 2 programs in narcolepsy, and study start-up activities for the idiopathic hypersomnia phase 2. We expect SG&A expenses to be similar to the first quarter of

2024, reflecting investments in LYBALVI promotional activities and the expansion of our psychiatry field sales force during the quarter.

Taken all together, we expect Q1 to be closer to breakeven on an EBITDA basis, with total revenues and profitability to increase significantly in the second quarter and remain fairly consistent overall in the second half of the year. These expectations for quarterly trending are reflected in the full-year financial expectations that I outlined a few moments ago.

We enter 2025 well-positioned financially with a strong balance sheet, a substantial commercial business and a continued focus on operational efficiency and profitability. We are investing in the initiatives that we believe will drive the future growth of the company and significant opportunities to create value for shareholders.

Todd Nichols:

2024 was an important year of execution of our commercial strategy and I am pleased that we achieved our expectations of proprietary net sales in excess of $1 billion in 2024, which reflected 18% year-over-year growth. Blair has taken you through the net sales performance so for my remarks, I will focus on underlying demand trends and our strategic focus areas and expectations for 2025.

Starting with VIVITROL. In 2024, VIVITROL net sales grew 14% year-over-year, driven by 6% underlying demand growth. This demand growth reflects strong traction in the

alcohol dependence indication, slightly offset by demand in the opioid dependence indication. The alcohol dependence indication represented approximately 75% of VIVITROL volume and it is where we focus our promotional efforts. As we look ahead to 2025, we expect VIVITROL demand to grow at mid-single digit rates and net sales to be in the range of $440 to $460 million.

Turning to our psychiatry franchise, which includes both ARISTADA and LYBALVI. We are focused on delivering growth across the franchise and are making strategic investments that we believe will drive underlying demand and profitability. For the ARISTADA product family, in 2024, ARISTADA net sales grew 6% year-over-year. In 2025, we expect underlying demand to remain fairly consistent compared to last year and ARISTADA net sales to be in the range of $335 to $355 million.

In 2024, net sales of LYBALVI grew 46% year-over-year, primarily driven by underlying TRx growth of 39%, with growth coming from both the schizophrenia and bipolar I disorder indications. Our promotional and direct-to-consumer advertising activities will continue to focus on driving adoption in both indications, utilizing tailored approaches to effectively target each segment.

During the year, we made significant progress in enhancing the access profile for LYBALVI in the commercial payer channel, with additional plans taking effect in January of this year. Looking ahead, in 2025, we expect these improvements will lead to a slight widening of gross-to-net adjustments to the mid-30s as we previously outlined. We are

pleased with LYBALVI's access profile today and will remain focused on additional opportunities to enhance our coverage going forward.

In 2025, we expect LYBALVI demand to grow by approximately 25% year-over-year and net sales to be in the range of $320 to $340 million.

For both LYBALVI and ARISTADA, as we enter 2025, we will continue to focus on the competitive dynamics in the antipsychotic space as we invest in, and expand, our psychiatry sales team in order to preserve a competitive share of voice for LYBALVI and reaccelerate growth for ARISTADA. We plan to complete our sales force expansion in the first quarter and expect contributions from the new sales positions to be tangible a few quarters from now. With the expansion of the sales team, an enhanced access profile for LYBALVI and a strong value proposition for both brands, we believe we are well positioned to achieve our 2025 goals for ARISTADA and LYBALVI. We look forward to sharing our progress with you.

Richard Pops:

We operate in commercial environments that require particular capabilities and scale. Our strategy, and our investments, focus on growth and profitability while enabling broad access to our medicines. We are well positioned to continue to be successful.

Our commercial business is the economic engine of the company. Its cash flows gives us the non-dilutive capital to invest aggressively in our development pipeline while maintaining profitability. And that pipeline is now at a stage where it has the potential to be transformative for the company. We see that becoming clear in 2025, with planned phase 2 data readouts for ALKS 2680 in narcolepsy type 1 and narcolepsy type 2.

ALKS 2680 is our novel orexin 2 receptor agonist. From the outset, we designed it with a future competitive profile in mind, incorporating things we have learned making medicines for patients in the real-world setting. For ALKS 2680, the goal has been to offer simple, once-daily dosing and, importantly, a range of doses to accommodate patients across narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia. Advancing multiple doses would offer patients and physicians the potential to adjust dosing to individual needs and preference, which is an important feature across many CNS disorders.

Let me spend a moment on these hypersomnolence disorders. Orexin is the master regulator of wakefulness. Narcolepsy type 1 is characterized by the absence or loss of orexin neurons in the brain. In NT1, an orexin 2 receptor agonist has the potential to replace the missing neuropeptide and restore normal wakefulness. Clinical data in NT1 provide strong evidence of this activity. Narcolepsy type 2 and idiopathic hypersomnia are associated with more normal orexin tone in the brain but may also be associated with aberrant signaling of the orexin system. A foundation of clinical data suggests that an orexin 2 receptor agonist can promote wakefulness in these patients too. Data from

our ALKS 2680 phase 1b study and an early proof-of-concept study conducted by others both demonstrated significant improvements in wakefulness in these disorders. At sufficient doses, we believe, based on data observed, that orexin 2 receptor agonists may have significant potential utility in NT2 and IH.

From a regulatory and development perspective, we are advancing ALKS 2680 pursuant to a strategy designed with the end goal in mind, which is FDA approval and competitive positioning. With proof-of-concept data from a robust phase 1b program in patients with narcolepsy in hand, last year, we moved into well-powered, parallel-design, confirmatory phase 2 studies in NT1 and NT2. Each study is designed to enroll 80 patients.

These studies will represent a significant additional increment of data for the entire field. When we are done, we will have 160 patients worth of data testing a range of doses over a multi-week period in the outpatient setting. These are studies of sufficient design and duration to more fully characterize safety, tolerability, efficacy and dose/response. These data will inform our ALKS 2680 phase 3 design and also begin to elaborate our potential competitive positioning in the class.

I'll give you a quick update on the progress we are making with Vibrance 1 and Vibrance 2, our phase 2 narcolepsy studies that we initiated last year. We have made significant progress with site initiations and enrollment, and I'm pleased with our momentum. We are enrolling patients in the U.S., EU and Australia. We expect data

from both those studies in the second half of this year. As we exit the first quarter, we should have sufficient line-of-sight to estimate completion timing with more specificity.

In idiopathic hypersomnia, we submitted an IND to the division of neurology at FDA and are expecting to initiate the phase 2 study in early spring. This study will be known as Vibrance-3 and it will share structural features of the narcolepsy studies – randomized, placebo-controlled double-blind, parallel design for 8-weeks. The doses will mirror our NT2 study at 10, 14 and 18 mg. Consistent with pivotal studies that have supported approval in idiopathic hypersomnia, we'll use the Epworth Sleepiness Scale as the primary endpoint and the idiopathic hypersomnia severity scale, or IHSS, as a key secondary endpoint.

So, in conclusion, for both narcolepsy and IH, we see the structure and execution of the phase 2 program as the springboard to phase 3, registration and commercial positioning. We are planning for success and preparing for the pivotal program with manufacturing, protocol design, and regulatory workstreams all underway. It's going to be an exciting and busy year.