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Alkermes Q1 2026 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 ended March 31, 2026. With me today are Richard Pops, our CEO, Joshua Reed, our Chief Financial Officer, Todd Nichols, our Chief Commercial Officer, and Blair Jackson, our Chief Operating 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. During the quarter, we closed the acquisition of Avadel Pharmaceuticals plc. The financial results announced today reflect the mid-February closing of the transaction and the integration of Avadel into our business, including six weeks of contribution from LUMRYZ, Avadel's once-at-bedtime sodium oxybate for the treatment of narcolepsy.

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, and now I will turn the call over to Richard for some opening remarks.

Richard Pops:

We had an excellent financial first quarter with another strong period of commercial execution and business performance. The quarter was also consequential in other ways. Perhaps most significantly, we completed the acquisition of Avadel, a key element of our strategy to become a leader in the sleep medicine space.

With LUMRYZ, we add a new, differentiated medicine to our portfolio, one that is early in its commercial life and has significant potential for growth. LUMRYZ addresses a clearly defined patient need and fits logically into our portfolio, consistent with our focus on medicines delivering meaningful clinical benefit to patients. From a financial standpoint, the acquisition further enhances our financial growth and provides additional resources and flexibility to advance our development portfolio.

Beyond the financial considerations, the acquisition allows us to establish a commercial footprint in sleep medicine now, well in advance of the potential approval and launch of alixorexton. This early presence enables us to engage directly with sleep specialists and other key stakeholders critical to ensuring access to prescribed medications. Building these relationships now provides a strong foundation to accelerate our potential launch trajectory for alixorexton.

Another consequential event occurred at the very end of the quarter, with the announced entry of Eli Lilly into this therapeutic space. This is an important external validation of the breadth of the scientific and commercial potential in developing new medicines targeting the orexin pathway. I think it underscores important aspects of this emerging therapeutic class, namely: the limited number of competitive entrants and the scarcity of available intellectual property around the chemistry, as well as the broad potential clinical and commercial opportunity. It starts with disorders of hypersomnolence and extends beyond that to a range of potential conditions in neurology, psychiatry and other rare diseases.

For Alkermes, we believe alixorexton and our other orexin development candidates represent substantial opportunities to advance patient care and drive significant value for shareholders. We have a clear strategy and we're well-positioned to advance these programs. Blair and I will provide an update on our development efforts at the end of the

call, but first I will turn the call to Todd and Joshua to review our commercial and financial performance for the first quarter.

Todd Nichols:

I'm pleased to report that we're off to a strong start to the year, with first quarter performance ahead of our expectations and solid execution across the commercial organization. It is exciting to note the evolution of our commercial team as our portfolio of commercial products expands. We now have commercial capabilities in three distinct categories: in addiction with VIVITROL, in psychiatry with ARISTADA and LYBALVI and now, following the closing of the acquisition of Avadel, in sleep medicine with LUMRYZ. The integration of the Avadel commercial team is progressing well and we entered the second quarter with the combined team fully in place. Looking ahead, with clear strategic priorities, a seasoned commercial team, and a portfolio of important medicines in addiction, psychiatry and sleep disorders, we are in a strong position to deliver on our performance goals for 2026.

Turning to our first quarter results. Net sales from our proprietary product portfolio increased 38% year-over-year to \$338.1 million, reflecting solid demand across our psychiatry and addiction portfolios and certain favorable gross-to-net adjustments during the quarter and six weeks of commercial contribution from LUMRYZ.

Starting with VIVITROL. Net sales in the first quarter were \$112.4 million. VIVITROL performance continued to be driven by 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 2026 in the range of \$460 to \$480 million.

For our psychiatry franchise, in the first quarter, net sales for the ARISTADA product family were \$93.8 million, reflecting solid underlying demand. In 2026, we continue to expect ARISTADA net sales in the range of \$365 to \$385 million.

LYBALVI net sales grew 32% year-over-year to \$92.4 million. Underlying TRx growth was 21% year-over-year, driven by sustained momentum in new patient starts and continued expansion in prescriber breadth. Gross-to-net adjustments were approximately 33%, which we expect will continue to widen into the mid-30s during the course of the year as we continue to build our market access profile. For the full year, we continue to expect LYBALVI net sales in the range of \$380 to \$400 million.

The first quarter results for these products benefited from gross-to-net favorability of approximately \$14 million, driven primarily by favorable patient mix. Approximately two-thirds of this favorability related to VIVITROL, and the remainder related to ARISTADA and LYBALVI. Across the brands, inventory levels in the channel were relatively stable in the first quarter of 2026. As a result, we expect Q1 to Q2 growth trends to generally track end-market demand.

Turning to our sleep franchise. We are now 10 weeks post close of the acquisition of Avadel. As we build our commercial presence in this space, we are pleased with feedback from the sleep medicine community regarding the LUMRYZ commercial organization, the utility and expected durability of the oxybate class and the differentiation of LUMRYZ within this category.

The LUMRYZ team is off to a strong start since joining Alkermes. For the six weeks following the close of the acquisition in mid-February, we recorded LUMRYZ net sales of \$39.5 million. For the full quarter, LUMRYZ generated approximately \$72 million of net revenue. We exited the quarter with approximately 3,600 patients on therapy and with solid momentum in new patient enrollments, which we expect to build on as we move through the year. For the full year, we expect LUMRYZ to generate total net sales in the range of \$350 to \$370 million. Of this, we expect Alkermes to record \$315 to \$335 million, reflecting the period since the mid-February close of the transaction.

In sleep medicine, our near-term focus is on driving growth and executing against the LUMRYZ opportunity while advancing our broader strategy in the space, including preparation for the potential launch of alixorexton. Narcolepsy and idiopathic hypersomnia represent multi-billion-dollar market opportunities, and our goal is to establish Alkermes as the leader in sleep medicine, based on deep expertise in this disease area and a differentiated and competitively positioned product portfolio.

With solid performance from our established franchises and the recent addition of LUMRYZ, we are operating from a strong position of increasing scale and diversification. As we move forward, our focus remains on disciplined execution, driving demand across our brands, and advancing our strategy in psychiatry, addiction, and sleep medicine. The first quarter was a strong start to the year, and we are well-positioned as we work toward achieving our 2026 objectives.

Joshua Reed:

In the first quarter, we delivered financial results that reflect continued growth across our proprietary product portfolio and the initial contribution from LUMRYZ following the close of the Avadel acquisition. Post-acquisition, our financial profile is further enhanced and diversified. We manage the business to drive significant operating cash flow and maintain a strong balance sheet, and we do so now with increased scale and flexibility. We are in a strong position to invest in the expanding development pipeline that will shape the future of our business.

Turning to our financial results. During the quarter, we generated total revenues of \$392.9 million. These results provide a solid foundation for the year. Today, we are updating certain non-cash elements of our 2026 financial expectations to reflect refinements to the purchase price accounting for the acquisition of Avadel. These adjustments improve our full year expectations for GAAP net loss and EBITDA.

For our portfolio of proprietary products, we generated net sales of \$338.1 million, ahead of the expectations we outlined on our fourth quarter call. As we move into the second quarter, we expect Q2 net sales from our proprietary portfolio, including a full quarter of revenues from LUMRYZ, in the range of \$385 to \$405 million.

Manufacturing and royalty revenues were \$54.8 million for the quarter, including revenues of \$27.3 million from VUMERITY and \$18.0 million from the long-acting INVEGA products.

Turning to expenses.

Cost of goods sold were \$61.6 million, which includes the purchase price accounting of LUMRYZ inventory. Recall that at closing, LUMRYZ inventory held by Avadel was marked to fair market value. Net of the LUMRYZ inventory step-up charge, cost of goods sold would have been \$48.9 million in Q1 of this year, compared to \$49.2 million in Q1 of the prior year. In the second quarter, we expect COGS to be in the range of \$85 to \$95 million, reflecting a full quarter of LUMRYZ sales and associated inventory step-up charge.

R&D expenses in the quarter were \$103.3 million, compared to \$71.8 million in Q1 of the prior year, reflecting the initiation of the alixorexton Brilliance phase 3 clinical

program in narcolepsy which began in the first quarter, the ongoing Vibrance 3 phase 2 study of alixorexton in idiopathic hypersomnia, and the phase 1 studies and development efforts for our next orexin 2 receptor agonist candidates, ALKS 7290 and ALKS 4510. In the second quarter, we expect R&D expenses to be in the range of \$110 to \$120 million.

SG&A expenses were \$264.6 million for the quarter, which included approximately \$55 million of costs associated with the closing of the acquisition of Avadel, including transaction expenses and share-based compensation. Excluding these one-time expenses, SG&A would have been \$209.4 million, compared to \$171.7 million in Q1 of last year, primarily reflecting the addition of the Avadel commercial infrastructure mid-quarter. As we look ahead to the second quarter, we expect SG&A expense to be in the range of \$210 to \$220 million.

During the quarter we also recorded amortization of intangibles of \$11.7 million and net interest expense of \$12.4 million.

In Q1, we generated GAAP net loss of \$66.5 million and EBITDA of minus \$30.1 million. We also generated positive Adjusted EBITDA of \$80.3 million, well ahead of our prior Q1 expectation of Adjusted EBITDA of \$30 to \$50 million due to higher-than-expected revenues and the timing of R&D expenses. Looking ahead to the second quarter, we expect Adjusted EBITDA to be in the range of \$100 to \$120 million.

Turning to our balance sheet. We ended the first quarter with approximately \$538 million in cash and total investments. To finance the acquisition of Avadel, we used approximately \$775 million of cash from our balance sheet and entered into term loans totaling \$1.525 billion due in 2031. We expect to pay down this debt quickly with cash flows from the business.

During the quarter, we also deployed \$28 million to repurchase approximately 1 million shares at an average price of approximately \$28 per share. We continue to have \$172 million of remaining share repurchase authorization.

As I mentioned, in connection with the purchase price accounting related to the Avadel acquisition, we have refined our expectations for several non-cash expense items, including the inventory step-up charge which flows through cost of goods sold and the amortization of intangible assets associated with LUMRYZ. These changes have a net positive impact on our 2026 expectations for GAAP net loss and EBITDA.

We now expect to expense approximately \$105 million of LUMRYZ inventory fair value step-up in 2026, compared to a prior estimate of approximately \$150 million. As a result, our 2026 cost of goods sold is now expected to be \$320 to \$340 million, an improvement from our prior estimate of \$365 to \$385 million.

For amortization of intangible assets, we now expect full-year amortization expense in the range of \$75 to \$85 million, compared to our previous estimate of \$95 to \$105 million. For income tax, we now expect no income tax expense or benefit for the year, from a prior estimate of an income tax benefit of \$20 million.

Taken together, these purchase price accounting adjustments improve our expectations for GAAP net loss, which is now projected to be in the range of \$70 to \$90 million, as well as for EBITDA, which is now expected to be in the range of positive \$105 to \$135 million. All other components of our 2026 outlook, including Adjusted EBITDA, remain unchanged.

Taking a step back, it was a strong start to the year and we look forward to carrying this momentum into the second quarter and beyond.

Richard Pops:

So, the commercial and financial elements of the business are strong. With expected revenue of more than \$1.7 billion and Adjusted EBITDA of more than \$370 million, we have the financial resources to invest aggressively in our pipeline and generate significant cash flow.

I think it's becoming increasingly clear that our orexin program has brought us to the threshold of substantial value creation. To date, we've developed—and shared with you—comprehensive clinical datasets across the first area of focus for this therapeutic

class: disorders of hypersomnolence. That dataset reflects the design and execution of a broad phase 2 program—randomized, controlled, multi-center, multi-week, across multiple doses and indications—using established clinical endpoints, as well as additional measures such as fatigue and cognition, that relate specifically to the brain circuitry we are activating.

At the same time, we are broadening our development efforts beyond disorders of hypersomnolence, leveraging our portfolio of orexin 2 receptor agonist candidates. In this area, more than most, we believe chemistry-based intellectual property represents an important strategic asset. Blair will speak in more detail about our expansion strategy and development plans, but first I want to update you on where we are today with alixorexton.

This year, our focus is on continuing the momentum we built in phase 2 to enroll the phase 3 Brilliance studies in narcolepsy. Phase 3, for us, is all about execution. We are on the path now to potential registration.

The Brilliance phase 3 program is now open for enrollment in narcolepsy type 1 and type 2, with site initiation and patient screening underway. Because of the strength of the phase 2 results, investigator interest in the studies is strong. We are working to enroll these studies quickly, with a sharp focus on quality and execution to support the strongest competitive positioning. From an operational perspective, the duration and

scale of the Vibrance phase 2 studies generated important and proprietary data that informed the design of our phase 3 program.

With alixorexton, we are building a broad and robust clinical data package across narcolepsy and idiopathic hypersomnia. In June, we will present data from the Vibrance-2 narcolepsy type 2 study at the annual SLEEP meeting in Baltimore. We reported the positive topline results in November, so much of the dataset will be familiar to you. Along with the positive outcome of the study, Vibrance-2 is important because it is one of a very small number of clinical studies ever conducted exclusively in patients with NT2. As such, it provides a depth of insight into the characteristics and variability of this population that is largely absent from the existing literature. The SLEEP meeting gives us an opportunity to share the data with the broader sleep community. One-on-one engagements with clinicians and investigators over the last several months have already given us a clear sense of the treatment community's high level of interest and excitement about these data.

For idiopathic hypersomnia, or IH, our Vibrance-3 phase 2 study is ongoing and on track to be completed in the fourth quarter of this year. We have initiated enrollment of a split-dose cohort of approximately 30 patients across sites in both the U.S. and Europe, with patients randomized to alixorexton or matching split-dose placebo. As a reminder, in IH the Epworth Sleepiness Scale and the Idiopathic Hypersomnia Severity Scale are the established and preferred clinical and regulatory endpoints. In addition to those

measures, Vibrance-3 also includes mean sleep latency assessed by the Maintenance of Wakefulness Test, which will help us characterize the durability of wakefulness over the course of the day.

The clinical development program for alixorexton has been deliberately designed to support strong competitive positioning, both in the quality of clinical data generated and in the breadth of potential dosing options and regimens being evaluated to address individual patient needs. We believe this approach positions alixorexton, if approved, to become the orexin of choice across both narcolepsy indications. Importantly, alixorexton has the potential to be first-in-class in narcolepsy type 2 and our lead in development in NT2 continues to widen.

In the meantime, while the orexin development story in narcolepsy continues to mature, with LUMRYZ, we now have an important new medicine being used in current clinical practice. Later this quarter, we expect to announce topline data from the LUMRYZ phase 3 REVITALYZ study in IH. Data from this double-blind, placebo-controlled, randomized withdrawal study, which enrolled approximately 150 patients, would serve as the basis for an sNDA submission with a potential launch in early 2028, if approved. This represents a potential growth opportunity for LUMRYZ in an underserved patient population, and we look forward to data this quarter.

Now, I'll turn the call over to Blair to provide an update on our expanding development work in our orexin portfolio. Beyond central disorders of hypersomnolence, there are many adjacent disease areas that may benefit from modulating the orexin pathway. We identified this opportunity early on and are moving aggressively with new molecules.

Blair Jackson:

As we outlined earlier in January, this year we are expanding our orexin development programs into disease areas outside of sleep medicine. We are doing so with two new molecules from our portfolio, ALKS 7290 and ALKS 4510. Each of these orexin 2 receptor agonists has been advancing through single- and multiple-ascending dose cohorts in healthy volunteers and we are pleased with the profiles we have observed to date. This year, our development plans take us into patient populations in ADHD and fatigue.

Early on, based on our emerging data and feedback from clinical investigators, we identified Attention Deficit Hyperactivity Disorder as one of the most compelling initial opportunities for orexin 2 receptor agonists outside of sleep medicine. ADHD is a common neurodevelopmental disorder characterized by persistent difficulty in maintaining attention and concentration, and is frequently accompanied by hyperactive and impulsive behavior. Despite the availability of some treatment options, many patients continue to experience residual symptoms, functional impairment, tolerability

issues, and adherence challenges, even when receiving current standard-of-care treatment.

Against that backdrop, Alkermes is working to advance the evidence base supporting the potential use of orexin 2 receptor agonists in ADHD. We have established a foundation of data from validated preclinical behavioral models, assessment of neurotransmitters and human EEG, that support our conviction in this program. Based on this foundation, we are initiating our first clinical studies of ALKS 7290 in adults with ADHD this year.

The first is a phase 1b, randomized, placebo-controlled proof-of-concept study designed to enroll approximately 50 adult patients. Participants will receive two weeks of treatment with ALKS 7290 or placebo. In this study, we will assess the safety and tolerability of ALKS 7290 along with the effects of treatment on translational measures where we expect to see more rapid changes, including quantitative EEG and certain neuropsychological performance measures. These assessments are designed to evaluate sustained attention, vigilance, and impulse control in a shorter duration study. For exploratory purposes, we'll also assess changes from baseline on established clinical ADHD scales. Results from this phase 1b study are expected in the fourth quarter of this year and will provide the first clinical data generated with an orexin 2 receptor agonist in patients with ADHD.

Enrollment in that study is already underway, with the first patients dosed in April. As enrollment in the phase 1b study progresses, we plan to initiate a well powered phase 2 study in adult patients with ADHD this summer. This randomized, double-blind study is expected to enroll approximately 300 patients and will evaluate ALKS 7290 versus placebo over a four-week treatment period. The primary endpoint will be change from baseline on the Adult ADHD Investigator Rating Scale. Data from this study, which we expect to complete in 2027, may serve as the foundation to advance to a potential registrational program in ADHD. We are excited to be the leaders in this exciting area of clinical development and we look forward to updating you on our progress.

For ALKS 4510, we are advancing in single- and multiple-ascending dose studies in healthy volunteers and plan to initiate a multi-dose phase 2a study later this year in patients with fatigue associated with multiple sclerosis and Parkinson's Disease.

Fatigue is one of the most common and burdensome symptoms in neurodegenerative disorders and remains a significant unmet need in MS and Parkinson's. Our interest in fatigue in these populations is also informed by observations from our phase 2 narcolepsy studies, where we saw improvements in patient reported fatigue that appeared distinct from effects on sleepiness or wakefulness alone.

Fatigue represents a novel area of pharmaceutical development and we will provide more details regarding the design of the development program as the phase 2 study

opens later this year. As we advance through the development program, our strategy will be stepwise, data-driven, and informed by interactions with regulatory authorities, as we seek to make a meaningful contribution to patient care.

Taking a step back, the potential utility of orexin 2 receptor agonists across a broad range of indications is a significant and striking opportunity. This will be the year that we generate a substantial new increment of data to the clinical evidence base supporting these potential opportunities.