July 24, 2024

Alkermes Q2 2024 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, 2024. With me today are Richard Pops, our CEO, Todd Nichols, our Chief Commercial Officer and Blair Jackson, our Chief Operating Officer.

During today's call, we will be referencing slides. These slides, 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 Blair for a review of the quarterly financial results.

Blair Jackson:

Our second quarter results reflect robust profitability and solid execution across our business, delivering double-digit year-over-year growth for our proprietary commercial product portfolio. The year is proceeding as planned and we enter the second half in a strong position with clear priorities to deliver on our 2024 financial expectations, which we are reiterating today.

For the second quarter, we generated total revenues of $399.1 million, driven by our proprietary product portfolio, which grew 16% year-over-year.

Starting with VIVITROL, net sales in the quarter were $111.9 million, compared to $102.1 million in the same period last year.

For the ARISTADA product family, net sales were $86.0 million, compared to $82.4 million for the same period last year.

For LYBALVI, net sales were $71.4 million, compared to $47.0 million for the same period in the prior year, which represented 52% year-over-year growth driven by robust underlying demand.

Across our proprietary commercial products, inventory in the channel returned to normal levels on a months-on-hand basis during the second quarter, following the drawdown we experienced in the first quarter of this year.

Moving on to our manufacturing and royalty business. In the second quarter of 2024, we recorded manufacturing and royalty revenues of $129.9 million. Revenues from the long-acting INVEGA products were $78.7 million, compared to $321.2 million for Q2 last year, which included $245.5 million of back royalties and related interest following the successful resolution of our arbitration with Janssen. As previously disclosed and reflected in our financial expectations for the year, our royalties on net sales of INVEGA SUSTENNA in the U.S. will end in mid-August of this year. We expect the impact on our third quarter results will be approximately $20 million. We will continue to receive royalties on net sales of INVEGA TRINZA and INVEGA HAFYERA in the U.S. and on the long-acting INVEGA products outside of the U.S.

Revenues from VUMERITY were $35.2 million, compared to $32.3 million for Q2 last year.

Now, I'll turn to our operating expenses and our financial results from continuing operations following the separation of our oncology business late last year.

Costs of goods sold were $61.5 million, compared to $63.2 million for Q2 last year.

R&D expenses were $59.6 million, compared to $68.2 million for Q2 last year. This reflects focused investments in our neuroscience development programs, primarily related to the ALKS 2680 clinical program and support activities for our proprietary commercial products. We expect R&D expense to remain relatively steady at this level through the end of the year.

SG&A expenses were $168.1 million, compared to $195.8 million for Q2 last year. The decrease was primarily driven by operational efficiencies and a number of non-recurring expenses that were recorded in the second quarter of 2023. Looking ahead, we continue to expect SG&A expenses to decrease in the second half of 2024, primarily reflecting the timing and mix of commercial promotion activities.

We continue to focus on driving profitability and during the second quarter we delivered GAAP net income from continuing operations of $94.7 million, non-GAAP net income from continuing operations of $123.4 million and EBITDA from continuing operations of $118.6 million.

Turning to our balance sheet. We ended the second quarter in a strong financial position, with $962.5 million in cash and total investments. In May, we completed of the sale of our Athlone, Ireland manufacturing facility to Novo Nordisk and received a cash payment of approximately $91 million for the facility and related assets. This transaction represents a key element of our multi-year strategy to drive operational efficiency and further align our infrastructure and cost framework with the anticipated needs of our

business. Additionally, as part of the $400 million share repurchase program authorized earlier this year, the company repurchased approximately 3.5 million of our outstanding shares during the quarter for an aggregate purchase price of $84.7 million, and we have since continued to be active repurchasing shares opportunistically in the market.

Taking a step back, we are pleased with the progress we have made, as we've continued to deliver on our multi-year plan to streamline the business and strengthen our financial and operating profile while advancing ALKS 2680 rapidly in the clinic. As we look at the second half of the year, we are in a strong financial position as we work to execute on our strategic priorities, drive momentum across our business and deliver robust profitability.

Todd Nichols:

We generated strong growth for our proprietary product portfolio in the second quarter. This was an important priority for our annual plan and we delivered on that objective. During the quarter, our team drove net sales of our proprietary product portfolio of 269.3 million dollars, reflecting 16% year-over-year growth. With two remaining quarters in the year, we are on track to achieve our previously announced financial expectations of proprietary net sales in excess of $1 billion in 2024.

I'll focus on LYBALVI, followed by quick updates on VIVITROL and ARISTADA. During the second quarter, we generated LYBALVI net sales of $71.4 million. Total prescriptions of LYBALVI grew 12% sequentially and 44% year-over-year to

approximately 55,300 during the quarter, reflecting strong underlying demand and continued expansion of prescriber breadth and depth.

Optimizing LYBALVI's access profile continues to be an important element of our long-term growth strategy for the brand, and compared to the beginning of the year, approximately 50 million additional lives now have improved access to LYBALVI. These enhancements are the result of our disciplined contracting strategy. During the quarter, we entered into a second major commercial contract as well as a contract that further improved formulary positioning on an important Medicare Part D plan, both of which took effect on July 1st. Similar to the commercial contract we announced last quarter, these contracts are not expected to significantly impact our anticipated gross-to-net adjustments.

Looking ahead, for the full year, we continue to expect LYBALVI net sales in the range of $275 to $295 million.

Turning to the ARISTADA product family, net sales in the second quarter were $86.0 million. While the long-acting antipsychotic market experienced some softness, ARISTADA new to brand prescriptions demonstrated encouraging growth. For the full year, we continue to expect ARISTADA net sales in the range of $340 to $360 million as we focus on commercial execution and continue to differentiate ARISTADA in the long-acting antipsychotics space.

Moving to VIVITROL. Net sales in the second quarter were $111.9 million, representing 10% year-over-year growth driven by underlying demand. VIVITROL performance continued to be largely driven by the opportunity in the alcohol dependence indication, which currently accounts for more than 75 percent of VIVITROL volume. For the full year, we continue to expect VIVITROL net sales in the range of $410 to $430 million.

With a solid Q2 now behind us, looking ahead, we expect to see typical summer demand patterns across our proprietary commercial product portfolio. Against that backdrop, our team will maintain its sharp focus on strong execution, highlighting the differentiating features of our medicines and driving uptake of our products. We look forward to sharing our progress with you.

Richard Pops:

We are now midway through the year and making excellent progress across the objectives we set for 2024. These objectives are: driving commercial and financial performance, advancing ALKS 2680 and our neuroscience development pipeline, completing the sale of our Athlone manufacturing facility and using our strengthened balance sheet to return capital to shareholders as opportunities present themselves.

Alkermes is now a biopharmaceutical growth company with multiple proprietary commercial products, an efficient operating structure and a development pipeline with significant potential value. This is the result of a multi-year evolution -- from our legacy

business as a partner to larger pharmaceutical companies, to an integrated pure play neuroscience company with a financial profile driven by the performance of our proprietary commercial portfolio. Our proven ability to bring new neuroscience medicines with significant medical and economic value to market is the foundation for new growth opportunities. This is an important transition, and we are well positioned to execute our plan to become a leader among neuroscience companies.

ALKS 2680 is becoming an important element of our growth strategy. ALKS 2680 is our novel, investigational, once-daily, oral orexin 2 receptor agonist for narcolepsy, currently in phase 2 development. During the quarter, we provided key data updates and met significant operational milestones in our expanding clinical program. As we enter Q3, ALKS 2680 is the only orexin agonist proceeding into phase 2 in both narcolepsy type 1 and narcolepsy type 2, supported by positive early clinical data in both indications.

Starting with our work in narcolepsy type 1 or NT1. During the quarter, we initiated our phase 2 study, Vibrance-1, a randomized, placebo-controlled, multinational study, evaluating the safety, tolerability and efficacy of three different doses of ALKS 2680. We are initiating sites and beginning to enroll patients in the study.

The Vibrance-1 phase 2 study was informed by data from our phase 1b proof-of-concept study. Last month, at the 2024 SLEEP meeting in Houston, we presented data from the full NT1 cohort from the phase 1b study. This medical congress gave us the opportunity to share the dataset with thought leaders and physicians within the broader

clinical community, along with patient advocacy organizations that play a key role in this therapeutic space. Feedback from these stakeholders bolstered our belief that the orexin 2 receptor agonist mechanism represents an opportunity to transform the treatment of narcolepsy.

In early April, we also announced positive topline data from the phase 1b cohorts with narcolepsy type 2 or NT2, and idiopathic hypersomnia. We plan to present additional data from the phase 1b study at the upcoming SLEEP Europe meeting in September. The data from the phase 1b in NT2 support advancement into a planned phase 2 study – which will be called Vibrance-2. Vibrance-2 will leverage much of the work we have done launching Vibrance-1, so we are moving quickly and expect to initiate that study and open it for patient enrollment toward the end of the summer.

NT2 represents a significant potential opportunity for ALKS 2680 and advancing in the clinic in this patient population is becoming an important differentiating feature for ALKS 2680.

A key element across the phase 2 program is the range of doses that will be evaluated: 4, 6 and 8 mg in NT1 and 10, 14, and 18 mg in NT2. Exploring this continuous dose range will allow us to comprehensively establish the dose response curve and the safety and tolerability profile of ALKS 2680 in narcolepsy type 1 and type 2. This range of doses also presents the potential to accommodate a spectrum of patient profiles and treatment objectives.

Beyond narcolepsy, data from across our phase 1 study of ALKS 2680 support our hypothesis that orexin 2 receptor agonists such as ALKS 2680 may have utility in treating a range of neurological disorders where excessive daytime sleepiness is a serious clinical consideration. The positive results in idiopathic hypersomnia, or IH, in the phase 1b study begin to build supporting evidence for this hypothesis. IH, by itself, represents a meaningful potential opportunity, and we are evaluating our strategic development plan in that under-served disease area.

But more broadly, the IH data further suggest that ALKS 2680 can drive meaningful changes in wakefulness in patients with relatively normal orexin levels and provide additional support for the evaluation of broader clinical uses for these agents. The work to explore these broader opportunities and advance our portfolio of preclinical orexin 2 receptor agonists is well underway. We have been active with our preclinical experimentation and new IP filings are in process. We plan to share more about our development strategy later this year.

I'll end with a brief update on our capital allocation strategy. The business is in a strong position to generate considerable excess cash flow while investing in the growth of our commercial portfolio and advancing our pipeline, as evident in our results year-to-date.

Based on the progress we are making in the business, measured against the current valuation, we see a substantial opportunity to capture value for shareholders. In Q2, we

activated our share repurchase program. We will continue to be active in the market informed by the ongoing needs of the business and evolving market conditions.

Across the business, we generated strong financial and operational performance in the first half of the year. Looking ahead, we have clear goals and priorities to advance the business and will maintain a sharp focus on execution and efficiency to deliver on those objectives.

We look forward to sharing our progress with you.