May 1, 2024

Alkermes Q1 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 March 31, 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:

Over the past two years we have been executing a plan to streamline our business and drive the growth of our proprietary products, our pipeline and our profitability. We entered 2024 as a pure-play neuroscience company with a top line driven by VIVITROL, ARISTADA and LYBALVI. Our 2024 financial expectations provided in February assumed Q1 seasonality followed by growth in the second quarter and beyond. This continues to be our expectation, and today we are reiterating our 2024 financial guidance.

Our first quarter performance reflects continued year-over-year growth of our proprietary product portfolio net sales, investment in LYBALVI and advancement of the ALKS 2680 development program, as well as our ongoing focus on efficient management of our cost structure to drive profitability. We are in a strong financial position, and confident in the growth opportunities ahead of us.

For the first quarter, we generated total revenues of $350.4 million, driven by our proprietary product portfolio which grew 9% year-over-year. This topline result also reflected the impact of a combined $10.2 million drawdown of inventory in the channel for our three proprietary products.

Starting with VIVITROL, net sales in the quarter were $97.7 million, driven primarily by the alcohol dependence indication, compared to $96.7 million in the same period last year.

For the ARISTADA product family, net sales were $78.9 million for the first quarter, compared to $80.1 million for the same period last year.

For LYBALVI, consistent with the expectations we outlined in February, net sales during the quarter were fairly flat sequentially at $57.0 million, which represented 50% year-over-year growth. Gross-to-net adjustments were stable sequentially.

Moving on to our manufacturing and royalty business. In the first quarter, we recorded manufacturing and royalty revenues of $116.8 million, compared to $72.9 million for Q1 last year. Revenues from the long-acting INVEGA products were $62.7 million, compared to $13.6 million for Q1 last year, reflecting the reinstatement of royalties related to these products in the second quarter of 2023. Revenues from VUMERITY were $31.3 million, compared to $28.9 million for Q1 last year.

Turning to expenses. Following the separation of our oncology business last year, expenses associated with the oncology business are considered discontinued operations. Today, I'll focus on results from continuing operations as those results are more relevant to the financial profile of the company going forward.

Our first quarter results reflect slightly elevated operating expenses, driven by the phasing of certain investments in clinical development, commercial support activities, labor-related costs and recognition of certain share-based compensation expenses. We expect that total operating expenses will decrease sequentially throughout the remaining quarters of the year.

Costs of goods sold of $58.6 million were flat compared to $58.2 million for Q1 last year.

R&D expenses were $67.6 million, compared to $63.8 million for Q1 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 decrease by approximately $10 million in Q2 and then remain relatively steady at that level through the end of the year.

SG&A expenses were $179.7 million, compared to $167.8 million for Q1 last year, primarily reflecting continued investment in the launch of LYBALVI. Looking ahead, we expect phased investments in selling and marketing initiatives to remain fairly consistent in the second quarter, followed by decreases in the second half of the year reflecting the timing and mix of promotional activities.

Within our non-cash expenses, across R&D and SG&A, we recorded $3.2 million and $6.2 million, respectively, of non-recurring share-based compensation expenses during the first quarter, related to the achievement of certain performance award criteria.

We continue to focus on driving profitability and during the first quarter we delivered GAAP net income from continuing operations of $38.9 million, non-GAAP net income from continuing operations of $76.2 million and EBITDA from continuing operations of $51.5 million, reflecting significantly enhanced profitability year-over-year, primarily driven by the growth of our proprietary commercial product portfolio, the separation of the oncology business completed during the fourth quarter of 2023, and our continued focus on operational efficiencies and disciplined expense management.

Turning to our balance sheet. We ended the first quarter in a strong financial position, with $807.8 million in cash and total investments and total debt outstanding of $290.1 million. Additionally, we expect to close of the sale of our Athlone, Ireland manufacturing facility to Novo Nordisk within the next day or two. In connection with the closing, Alkermes will receive a one-time cash payment of approximately $91 million. This transaction represents a significant element of our multi-year program to drive operational efficiency and further align our infrastructure and cost framework with the anticipated needs of our business.

Taking a step back, our first quarter results were largely consistent with our expectations, and we believe provide a solid foundation for growth through the rest of the year. We expect topline growth to accelerate into the second quarter and are pleased with our trajectory thus far. We remain focused on disciplined management of our expenses and expect enhanced profitability as we move through the remaining quarters of the year.

Todd Nichols:

In the first quarter, net sales from our proprietary product portfolio grew 9% year-over-year, even with meaningful reductions in inventory in the channel for all three products. As we enter the second quarter, we are reiterating our 2024 financial expectations for each of our three proprietary products: LYBALVI, ARISTADA and VIVITROL.

Starting with LYBALVI. During the first quarter, we generated net sales of $57.0 million, which was relatively flat sequentially compared to the fourth quarter, consistent with our expectations. Total prescriptions of approximately 49,600 during the quarter reflect underlying prescription growth of 6% sequentially and 50% year-over-year, as well as continued expansion of prescriber breadth. This growth in demand was partially offset by a decrease in inventory in the channel equal to approximately $2.3 million. During the first quarter, LYBALVI continued to be the fastest growing oral brand in the market on a prescription basis.

Optimizing LYBALVI's access profile is an important element of our long-term growth strategy for the brand. Payor coverage across Medicare and Medicaid is established, with most patients having a pathway to access. For the commercial payor channel, our disciplined contracting strategy is playing out as we seek to maximize net sales of LYBALVI while expanding patient access. We recently enhanced the access profile for LYBALVI through selective contracting with a large pharmacy benefit manager to improve formulary positioning. This contracting is not expected to significantly impact our anticipated gross-to-net adjustments this year. We have additional opportunities to

further enhance commercial payor access for patients and believe we are well positioned to continue to execute our strategy.

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 first quarter were $78.9 million, reflecting pronounced seasonality in prescriptions and a substantial decrease of inventory in the channel equal to approximately $3.6 million. We expect inventory levels to approach more normal levels in the second quarter. We continue to focus on highlighting ARISTADA's differentiated features and supporting clinical data. For the full year, we continue to expect ARISTADA net sales in the range of $340 to $360 million.

Moving to VIVITROL. Net sales in the first quarter were $97.7 million, reflecting normal seasonal trends in patient flow and a decrease of inventory in the channel equal to approximately $4.3 million. VIVITROL performance continues to be largely driven by the opportunity in the alcohol dependence indication, which currently accounts for approximately 75 percent of VIVITROL volume. Alcohol dependence is an important growth opportunity, and our team is energized about driving awareness and uptake in that under-served disease area.

Looking ahead to the full year, we continue to expect VIVITROL net sales in the range of $410 to $430 million.

With the first quarter now behind us, we have a solid foundation for growth into the second quarter and the second half of the year. For all three of our products, inventory levels have started to rebound in recent weeks and prescription growth has been in line with our Q2 expectations. Our commercial team is focused on execution across our portfolio and we look forward to sharing our progress.

Richard Pops:

Alkermes is now a profitable, pure-play neuroscience company with an advancing pipeline. This profile drives our objectives for 2024: commercial execution, advancing ALKS 2680 in the clinic and expanding our development pipeline. Blair and Todd covered the financial and commercial elements. I am going to spend a few minutes on recent developments within our R&D pipeline, particularly ALKS 2680, our novel, once-daily, oral, orexin 2 receptor agonist in development for narcolepsy.

Starting with our progress in narcolepsy type 1 or NT1. Based on the biology, the core of the ALKS 2680 development program is in NT1, which is associated with an absence or significant deficiency in orexin levels.

We are moving quickly in this indication. Last year, we generated important proof-of-concept data in patients with NT1. Based on the compelling initial data from our first four patients, we made the decision to accelerate phase 2 planning. Toward year-end, the data from the full NT1 cohort of 10 patients reinforced our conviction in that decision.

We entered 2024 with work well underway to finalize the phase 2 protocol, manufacture clinical supply of the phase 2 dosage strengths, and interact with FDA and clinical study sites and investigators. These activities culminated in the recent initiation of Vibrance-1, a phase 2, randomized, placebo-controlled, multinational study, which we announced last week.

Vibrance-1 is planned to enroll approximately 80 subjects, randomized to single daily doses of either 4, 6 or 8 mg of ALKS 2680 or placebo over a six-week double-blind treatment period. Data from the study will further characterize the safety and efficacy profile of ALKS 2680, utilizing well-established efficacy endpoints including the maintenance of wakefulness test, or MWT, Epworth Sleepiness Scale, and weekly cataplexy rates. We expect the study will take approximately one year to fully enroll. As we gain more experience with clinical site initiations and patient enrollment trends, we will look to put a finer point on the timelines.

As we launch this phase 2 study, we are also looking forward to sharing additional data from the full NT1 cohort from the phase 1b study with the clinical community at the SLEEP 2024 meeting in June. These data will include safety, tolerability and MWT improvements for the full cohort of 10 patients, as well as our first presentation of improvements in subjective levels of sleepiness as measured by the Karolinska Sleepiness Scale or KSS.

Narcolepsy type 2 or NT2, represents another significant potential opportunity for ALKS 2680. Last month, we announced positive topline data from the phase 1b cohorts in NT2 and idiopathic hypersomnia. In these cohorts, participants were randomized in a four-way crossover design in which each participant received single, oral doses of 5, 12 and 25 mg of ALKS 2680, and placebo, with washout periods between each treatment. ALKS 2680 was generally well tolerated and resulted in clinically meaningful and statistically significant improvement in wakefulness, as measured by MWT sleep latency scores, at all doses tested. We refer you to the press release that we issued on April 9th for more details related to the safety, tolerability and efficacy observed in these cohorts in the phase 1b study.

Importantly, the data showed dose-dependent effects and a pharmacodynamic profile that support advancement into a planned phase 2 study in NT2 patients – which will be known as Vibrance-2. We recently finalized our dose selection for that phase 2 study and plan to move forward with 10, 14 and 18 mg doses of ALKS 2680.

ALKS 2680 is currently the only orexin 2 receptor agonist moving into later-stage clinical evaluation in narcolepsy type 2. We are working to initiate the Vibrance-2 as quickly as possible, which we expect to be in the second half of 2024.

The data from the phase 1b cohorts validate our hypothesis that an orexin agonist with appropriate pharmaceutical properties has the potential to provide clinical benefits for both NT1 and NT2 patient populations. Importantly, the data also demonstrate that

orexin 2 receptor agonists such as ALKS 2680 may have utility in treating other disorders in patients without known orexin deficiency. This represents a significant opportunity to evaluate expansion into broader disorders where excessive daytime sleepiness is a feature. To explore these opportunities, we continue to advance our portfolio of preclinical orexin 2 receptor agonists and recently nominated our next candidate which is now in IND enabling studies. We look forward to sharing additional details about our plans in this space later this year.

Four months into the year, we are continuing to execute against our strategic priorities. Across the commercial business, the team is focused on delivering growth and strong financial performance. The ALKS 2680 development program is well on track and represents a potentially transformative opportunity for the business. And, consistent with the capital allocation framework we unveiled earlier this year, we continue to evaluate opportunities for external business development and to return capital to shareholders.

We look forward to sharing our progress with you.