October 24, 2024

Alkermes Q3 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 September 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 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 Todd for a review of the commercial portfolio.

Todd Nichols:

We generated strong growth for our proprietary product portfolio in the third quarter. During the quarter, our team drove aggregate net sales of $273 million, reflecting 18% year-over-year growth. With three quarters now complete, we are on track to achieve our previously announced financial expectations of proprietary net sales in excess of $1 billion in 2024.

Starting with VIVITROL, net sales in the third quarter were $113.7 million, representing strong year-over-year growth of 14%, driven by underlying demand and growth in the alcohol dependence indication. For the full year, we expect VIVITROL net sales toward the high end of our previously announced range of $410 to $430 million.

Turning to the ARISTADA product family, net sales in the third quarter were $84.7 million. During the quarter, we continued to see some softness in the overall schizophrenia long-acting antipsychotic market, which we expect will persist through the end of the year. With that in mind, we expect ARISTADA net sales to be toward the lower end of our previously announced range of $340 to $360 million for the full year.

For LYBALVI, during the third quarter, we generated net sales of $74.7 million. Total prescriptions of LYBALVI grew 5% sequentially and 37% year-over-year to

approximately 57,500 during the quarter, reflecting strong underlying demand and continued expansion of prescriber breadth and depth.

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

LYBALVI is an important treatment option in the schizophrenia and bipolar I disorder space, differentiated by its efficacy and safety profile and long-term data. To support the long-term growth of LYBALVI, we are focused on executing our strategy to optimize its access profile and maximize net sales and profitability. We are pleased with our progress this year. This past quarter, another important commercial payer enhanced access effective October 1st, and discussions with other key payers are ongoing. As we have previously discussed, as we expand commercial access, we expect both higher unit volume and fulfillment rates as well as higher gross-to-nets. Over the course of next year, we expect gross-to-net adjustments will move into the mid-30s.

As we enter 2025, we will be focused on competitive dynamics in the antipsychotic space. As we work to maximize the opportunities for both LYBALVI and ARISTADA, our most effective investment is personal promotion via our field force, and we plan to increase our investment there to preserve a competitive share of voice. We are maintaining a sharp focus on executing our commercial strategy and believe we are well positioned to drive growth across our portfolio. We look forward to sharing our progress with you.

Blair Jackson:

The third quarter marks an important inflection point for the company as we have worked over the last several years to transition the business to a financial profile driven by the performance of our proprietary commercial products and an efficient operating structure that has been realigned to support the needs of the business and drive profitability.

Q3 was another productive quarter for Alkermes highlighted by the strong performance of VIVITROL and LYBALVI and our continued focus on operating efficiency. With three quarters of solid results behind us, we are reiterating our financial expectations for 2024.

For the third quarter, we generated total revenues of $378.1 million, driven by our proprietary product portfolio, which grew 18% year-over-year.

Starting with VIVITROL, net sales in the quarter were $113.7 million, compared to $99.3 million in the same period last year. For the ARISTADA product family, net sales were $84.7 million, compared to $81.8 million in Q3 last year. And for LYBALVI, net sales were $74.7 million, compared to $50.7 million for the same period last year.

Across our proprietary commercial products, inventory remained stable on a months on hand basis.

Moving on to our manufacturing and royalty business. In the third quarter, we recorded manufacturing and royalty revenues of $105.1 million. Revenues from the long-acting INVEGA products were $58.4 million, compared to $76.1 million for Q3 last year. As previously disclosed and reflected in our financial expectations, our royalties on net sales of INVEGA SUSTENNA in the U.S. ended in mid-August of this year. 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 $32.6 million, compared to $34.6 million for Q3 last year.

Due to the timing of manufacturing activities, we did not record any manufacturing revenues related to FAMPYRA during the quarter, but we expect FAMPYRA revenues of approximately $25 million in Q4. This will represent the conclusion of our manufacturing obligations and associated revenues related to FAMPYRA.

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 $63.1 million, compared to $61.5 million for Q3 last year.

R&D expenses were $59.9 million, compared to $64.9 million for Q3 last 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. We expect R&D expense to remain in this range through the end of the year.

SG&A expenses were $150.4 million, compared to $156.4 million for Q3 last year. Looking ahead, we expect SG&A expenses to decrease in the fourth quarter, primarily reflecting the timing and mix of commercial promotion activities.

We continue to focus on driving profitability and during the third quarter we delivered GAAP net income from continuing operations of $92.8 million, non-GAAP net income from continuing operations of $121.4 million and EBITDA from continuing operations of $112.3 million.

Turning to our balance sheet. We ended the third quarter in a strong financial position, with $927.8 million in cash and total investments. During the quarter, we deployed approximately $116 million to repurchase 4.4 million shares as part of the $400 million share repurchase program authorized earlier this year. With $200 million of remaining authorization, going forward, we may opportunistically repurchase shares dependent on market conditions and the capital needs of the business.

We are in a strong financial position and have made solid progress across the business as we execute against our strategic, operational and financial priorities for 2024.

Switching gears, I'm going to a spend a minute on our plans for next year.

In 2025, we plan to manage the business to deliver significant profitability and cash flow while increasing our investment in the growth opportunities that we believe will be the key drivers of shareholder value. We will provide detailed expectations in February, but today I'll highlight a few considerations to keep in mind. In 2025, we expect our topline will be driven primarily by growth of our proprietary commercial portfolio, reflecting the expected dynamics within our royalty and manufacturing revenue streams, namely: the previously announced conclusion of royalties on U.S. net sales of INVEGA SUSTENNA and FAMPYRA manufacturing revenues in 2024, and the planned transition of VUMERITY manufacturing to Biogen in 2025. Collectively, we expect these factors will impact royalty and manufacturing revenues by approximately $200 million in 2025. Primarily driven by our early success in the clinic with ALKS 2680, we expect our overall operating costs will increase modestly as we advance the ongoing ALKS 2680 phase 2 studies and expand into idiopathic hypersomnia; and, as we increase our investment in our psychiatry commercial footprint to support the growth of LYBALVI and ARISTADA. Taken together, we are committed to maintaining a robust cash generating business and expect to deliver profitability of more than $200 million in EBITDA next year.

Our 2025 financial profile will demonstrate the significant transformation of the company over the last several years and serve as a strong foundation for future growth and financial performance.

Richard Pops:

2024 has been a key transition year for the company. We entered the year as a pure play neuroscience company, with a strong top line and streamlined cost structure, and planning for our final year of cash flow from royalties related to INVEGA SUSTENNA. Our focus in 2024 has been to manage the business to generate a substantial amount of cash and demonstrate the profitability inherent in the business, while we advanced the ALKS 2680 clinical program to get a sense of its potential.

We now have positive phase 1b data in hand for ALKS 2680 in patients with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia. These data underscore the differentiated profile of ALKS 2680 in the orexin 2 receptor agonist therapeutic category. And, based on the successful outcome of the phase 1b, we have advanced quickly into a phase 2 program.

As we prepare to enter 2025, as you heard from Blair, we plan to manage the business to generate significant cash and profitability. That's an important priority for us. We believe that the way to create significant shareholder value is through deploying capital toward development candidates with significant potential and a favorable benefit/risk profile. New medicines. We have clinical proof-of concept data supporting the potential of ALKS 2680 in narcolepsy and IH, and preclinical data suggesting the potential applicability of orexin 2 receptor agonists in other disease categories. So, our focus is on aggressively moving forward R&D initiatives that can drive meaningful shareholder value.

Two weeks ago, we provided a comprehensive update on the ALKS 2680 program and other orexin candidates advancing in our development portfolio. The replay and materials from that portfolio strategy review event are still available on our website, so I'll be brief today.

Our ALKS 2680 phase 2 studies in NT1 and NT2 are underway, with sites actively screening and enrolling patients. As we announced earlier this month, we expect data from both studies in the second half of 2025. We are continuing to activate additional clinical trial sites to further support enrollment and to provide a strong operational foundation for potential phase 3 studies. We are preparing for success, with the goal of moving as swiftly as possible from phase 2 into registrational studies.

The scientific foundation supporting this class of investigational medicines is growing. Orexin-based therapies have the potential to transform how narcolepsy and IH are treated. With many molecular design parameters requiring optimization, we believe that different molecules, ours and others, will demonstrate different pharmaceutical properties in the clinic. To date, we are one of just two companies that have presented data in patients with hypersomnolence disorders, we like our positioning in this competitive landscape. ALKS 2680 is the only entrant advancing to phase 2 in NT1, NT2 and IH based on data in patients. The phase 2 data we expect next year has the potential to be a transformative catalyst -- in this development space and for the company.

The implications of this biology and pathway may extend beyond hypersomnolence disorders. The orexin system is associated with the activation of multiple downstream neurotransmitters and neurocircuitry. Our preclinical data suggest that orexin-based pharmacology has the potential to extend to multiple CNS disease settings where sleepiness, fatigue, cognition and mood are prominent clinical features. We are leveraging this understanding, pursuing a multi-faceted research program designed to identify the most promising lanes of development. We recently shared a selection of our preclinical data that demonstrated benefit with orexin 2 receptor agonists in highly translatable models in symptomatic domains related to mood, attention and impulsivity. We are continuing these efforts to map and prioritize the disorders where we see the greatest opportunity to drive benefit for patients and for the company. In parallel, we are planning to advance two additional orexin 2 receptor agonist candidates into first-in-human studies next year. These candidates share certain features of ALKS 2680 in terms of required potency and selectivity, but we believe they will have distinct pharmaceutical properties. We will characterize these properties in our early clinical experience. This will inform our development strategy for the portfolio.

We will exit 2024 with a clear strategy to create value for shareholders and are carrying a great sense of momentum into 2025.